REMARKS

Claims 12–23 are pending. Claim 12 has been amended, and Claims 13-23 are new. No new matter has been added. For example, the subject matter of new Claims 13-16 is disclosed in FIGURES 7-10 and page 13 of the application as originally filed.

Claim 12 was rejected under ¶ 112 as vague due to the use of "and/or" which has now been eliminated. Claim 12 was also rejected as anticipated by Gerding. This rejection is respectfully traversed for the reasons discussed below.

Problem Recognition Is Patentable Here

This record makes clear that nosocomial infections have been a long-standing problem (see, e.g., the inventor's article, "*Infection Control in Medication Storage Bins,*" Tab A). It is equally clear that prior solutions to such infections have not tended to focus on medical cart contamination as a cause; to the extent any thought has been given to this, prior art efforts have focused on bin cleaning (*id*; see also Bober and Bradley Letters and inventor survey, Tab B). Unfortunately, bin cleaning not only has proven inconsistent and/or ineffective, but can also have a deleterious impact on bin integrity, and may compromise the medication cart's ability to resist nosocomial infections (*id.*) To Applicant's present knowledge, no attempted prior art solutions have used a disposable barrier such as a disposable liner to address bin contamination and the threat of nosocomial infections, as with the presently claimed invention.

Patentability can be shown through problem recognition, where the true cause of the problem was not suggested by the prior art. *Cross Medical Products, Inc. v. Medtronics Sofamor Danek Inc.*, 424 F.3d 1293, 1323 (Fed. Cir. 2005) (invention non-obvious because one of ordinary skill in the art would not have chosen the solution without recognizing the true cause of the problem, a cause not suggested by the prior art); *Application of Sponnoble*, 405 F.2d 578, 585 (CCPA 1969) ("It should not be necessary for this court to point out that a patentable invention

may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified."). *See also Application of Anniston*, 272 F.2d 948, 949 (CCPA 1959) (citing U.S. Supreme Court in *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 67 (1959) (the inventive act which entitles an applicant to a patent resides as well in the discovery of the source of the trouble as in the application of the remedy); *Cardiac Pacemakers, Inc. v. St. Jude Med. Inc.*, 381 F.3d 1371, 1377 (Fed. Cir. 2004) ("There can of course arise situations wherein the identification of the problem is itself the invention."). Here, while the general problem of nosocomial infection was recognized, the specific problem of bin contamination as a root cause of such infections, or how to appropriately address bin contamination, was never addressed by the prior art.

The prior art failed to recognize that bin cleaning is not generally effective, and can actually exacerbate the potential for nosocomial infections, due to plastic degradation when contacted by harsh cleaners (*Infection Control in Medication Storage Bins, supra*). Perhaps due to the failure to recognize this problem, the solution of providing a secondary disposable barrier, such as disposable liners, never surfaced in the prior art.

That the foregoing is true is supported by five declarations, attached as Tab C, from knowledgeable doctors and pharmaceutical personnel (see attached Declarations of Messrs. Bhatt, Davis, Garcia, Raper and Carrell). These highly knowledgeable persons explain that:

- the cross-contact between "noncritical" patient care items such as medication carts and bins, on the one hand, and the "critical" or "semicritical" items, on the other, present in hospitals is an underestimated problem (*id.*, ¶3);
- there are no uniform cleaning standards for such carts and bins, which are often reused without cleaning (*id*); hospital personnel have long failed to recognize the role medication carts play in the transmission of nosocomial infections (*id.*, ¶4);

- "vending machine" type medication carts such as "Pyxis," "Omnicell" or ADMs (Automatic Dispensing Machines) have been used, but have always used removable, heavy plastic "liners" which fit within the drawers, whose cleaning may not remove drug-resistant pathogens (*id.*, ¶5);

- nosocomial infections may be better resisted by using carts having liners dedicated to an individual patient, which may be dispensed with following patient use (*id*); and

- Holmes (similar to Gerding[1]) fails to address the solutions of the present invention but, instead, perpetuates the flawed prior art carts, as it fails to address cross-contamination issues.

The Anticipation Rejection (Gerding)

Gerding fails to disclose or suggest the use of sanitary liners for combating nosocomial infections, as recited in independent Claim 12. Gerding's objects are to "provide an improved apparatus for the preparation, organizing, transporting and distribution of pharmaceuticals" which "enables the efficient preparation and distribution of single dosage quantities of medicine" (Gerding, col. 2, lines 14-21). Gerding says nothing about combating nosocomial infections. While there is a single sentence in Gerding that container 178 "can be used once and discarded" (col. 6, lines 44-45), Gerding says nothing about making the liner sanitary – which is necessary given the contamination that can come from cross-contact issues and failure to apply uniform cleaning standards, as discussed above.

For the foregoing reasons, Applicant respectfully requests an allowance of Claims 12-21.

Respectfully submitted,

s/Michael P. Mazza
Michael P. Mazza
Registration No. 34,092

[1] The Tab C declarations were originally prepared in response to a rejection made in the parent application (U.S.S.N. 10/246,058, filed 9/18/02) based upon Holmes. They are applicable to Gerding, here, as well.

686 Crescent Blvd.
Glen Ellyn, IL 60137-4281
P: 630-858-5071
F: 630-282-7123
Email: mazza@mazzallc.com
Attorney for Applicant

TAB A

Joint Commission International Center for Patient Safety

Infection Control in Medication Storage Bins

Although an organization's medications that are protected inside sealed packages rarely carry infections, the bins storing these medications may harbor infections or nosocomial pathogens. These pathogens can be a potential source of indirect contamination when a nurse or other staff member touches the bin and carries the packaged medication and then touches a patient. Patients immunocompromised by AIDS, transplantation, or cancer therapy and patients with increased susceptibility to infection as a result of diabetes, trauma, or severe burns are at particular risk. Staff needs to be aware of the possible infection control (IC) risks and take steps to minimize the risks.

Standard **IC.2.10** requires organizations to conduct surveillance, collect data, and identify trends in IC. In addition, Medication Management standard **MM.2.20** requires an organization to periodically inspect medication storage areas, in accordance with its policy, to ensure that medications are properly and safely stored. Each compartment or *medication bin* of an automated medication distribution system may be designed to contain one specific medication or all an individual patient's medications for a 24-hour period.

Pharmacy staff in a 300-bed general medical/surgical hospital investigated the degree of contamination in the hospital's medication bins. The study found that 84% of the bins tested were contaminated with bacterial and/or mold growth. Although most of the eight microorganisms identified were generally harmless environmental contaminants (indicating a poor degree of cleanliness), some (such as coagulase-negative staph and pseudomonas) were capable of causing serious infection.(1) Other studies have identified the viability of several clinical and environmental bacteria and fungi on fabrics and plastics commonly used in hospitals.(2–4)

There is a general lack of awareness about the potential problem of dirty medication bins and the potential for spread of infections. Five key strategies to minimize infection risk from medication storage bins follow.

1. Identify potential risk in your organization. Ask pharmacy, nursing, and IC staff for their observations about how medication bins are used, whether staff uses gloves, whether the bins are carried into patient rooms, and under what circumstances the bins are cleaned or replaced. Organization staff may even want to take swab samples to test for the presence of bacteria or molds.
2. Establish or review a cleaning procedure for medication bins. Many organizations clean a bin only when it is dirty beyond use or when a regulatory or accreditation body is expected. Organizations should clean bins on a regular basis, such as on patient discharge, regardless of their appearance. Decide who is responsible for cleaning (nursing or pharmacy) and when. For example, the cleaning procedure could be added to the regular cart filling tasks of the pharmacy. Include in the procedure the cleaning of automated dispensing systems as well as nurses' medication carts. Provide staff education on the importance of maintaining clean medication bins to reduce infection risk. And, as always, emphasize hand hygiene and proper glove use.

   If a bin is taken into an isolation room, it should not be used for another patient until it is properly disinfected. Organizations must use a disinfecting agent that is broad enough to kill the major organisms identified or those that are potentially serious. Plain alcohol is generally insufficient. Most disinfectants that are effective must be allowed to air dry for 10 minutes after application. Check with the manufacturer, especially with automated dispensing machines, for suggestions on disinfecting products that won't damage the bin or machine over time.
3. Consider the use of bin liners. Although the risk of contaminants still exists with bin liners, it is significantly reduced. Bin cleaning can be costly, time-consuming,

Priority

Just Released Publication

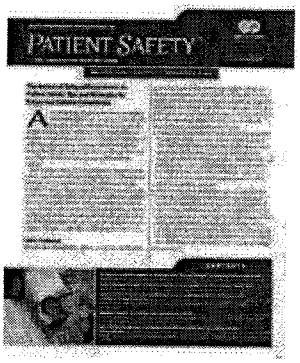
Patient Safety Case Studies Wanted

and damaging to the bins over time. Disposable liners provide a consistent, convenient, and cost-effective method for maintaining clean bins. Bin liners can be replaced on a regular basis and whenever the liner becomes soiled.

4. Create a closed system for preparing intravenous (IV) medications. Preparing IV medications under a laminar flow hood keeps them in a relatively sterile environment. The laminar flow prevents objects from settling on surfaces, making sure that bacteria do not settle on the IV bag or its contents. After admixing the medications in the laminar flow hood, place a sterile cap (not a foil cap) on the IV bag while still under the hood. In this way, staff creates a closed system in which bacteria and other infection agents cannot get into the IV bag. So even if the IV bag is placed in a nonsterile medication bin, the medication will not become infected. (This process is required under standard MM.4.20.)
5. Monitor the state of medication bins for cleanliness. IC staff can add medication bin status to their walk-rounds and ensure that the medication bins are cleaned properly. However, changing pharmacist and nurse behavior to consistently clean the bins will be the greatest challenge. To prove medication bin cleanliness, consider documenting that medication bins have been cleaned, use the data in trend analysis, and benchmark the values.

References

1. Hannan R.E., Funk D.I.: Patient medication drawers; An overlooked fomite (An evaluation of medication drug bins as a potential source of nosocomial pathogens).An abstract of the "2004 ASHP Midyear Poster."
2. Neely A.N., Maley M.P.: Survival of enterococci and staphylococci on hospital fabrics and plastics. *J Clin Microbiology* 38:724–726, Feb. 2000.
3. Neely A.N.: A survey of gram-negative bacteria survival on hospital fabrics and plastics. *J Burn Care Rehabil* 21:523–527, Nov.–Dec. 2000.
4. Neely A.N., Orloff M.M.: Survival of some medically important fungi on hospital fabrics and plastics. *J Clin Microbiology* 39:3360–3361, Sep. 2001.

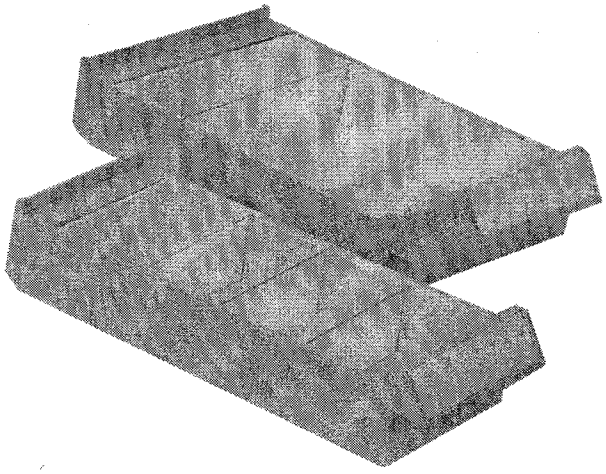


Source: Joint Commission Resources: Infection control in medical storage bins. *Patient Safety* 5:11, Jun. 2005.

The Joint Commission | Joint Commission Resources | Joint Commission International

Your small friend, indeed®
Health Care Logistics® INC.

An Evaluation of Medication Drug Bins as a Potential Source of Nosocomial Pathogens



INTRODUCTION

Infection control in health care institutions is the single most important reason for the prevention of morbidity and mortality associated with nosocomial infections. Hundreds of thousands of American patients suffer the consequences of nosocomial infections each year. Such consequences range from the inconvenience of having to take additional medications for treating an infection to death. Aside from this human cost is the significant economic encumbrance that these infections place on society, including not only an apparent increase in health care resource usage but also the indirect costs associated with the loss of productivity of patients and caregivers.[1]

A facility in which a large number of people having a vulnerable health status and spending a significant amount of time in during the course of the day can be defined as an institutional setting. The time that people spend together in these settings may be continuous for days, weeks, or even months. Child care centers, schools, hospitals, long-term care facilities (including nursing homes and assisted living centers), military installations, and prisons are all examples of institutions. Although they vary greatly in both the population influences and the length of stay of the participants, they all have a common element that being because of confinement, an opportunity of the transmission of infectious agents. Therefore, a variety of infection control practices are important.[2] One third of all nosocomial infections may be preventable, and they are frequently caused by organisms within the institutional environment.

Microorganisms associated with infections manifested in institutional settings include bacteria, viruses, fungi, parasites, and nematodes. Transmission routes may be direct or indirect contact with contaminated fomites or air. One means of reducing nosocomial infections is to identify previously unrecognized fomites and then provide some measure of infection control for those contaminated objects.

Drug bins used to transport and deliver medications to patients by nurses may be an unrecognized fomite and may contribute to the spread of nosocomial infections in an institution. Pharmacy needs to be aware of the possible contamination of drug bins with microorganisms capable of causing nosocomial infection in patients who are compromised.

With this as a basis, a study was initiated in a 300-bed general med/surg hospital to investigate the degree of microbial contamination in dirty drug bins and compare this to the use of bin liners as an adjunct to minimize the potential for nosocomial infection spread.

METHODOLOGY

Fifty-five (55) drug bins used to transport and administer drugs to patients in a 300-bed general med/surg hospital were sampled for bacterial growth.

The drug bins were randomly sampled on medication carts on three active hospital units. Thirty (30) random samples were taken from a general med/surg unit. Fifteen (15) random samples were taken from a MICU unit. Ten (10) random samples were taken from a surgical unit.

Twenty-five (25) bin liners were sampled from a batch of prototype liners provided by Health Care Logistics to the hospital. A similar procedure was used in the sampling of both the drug bins and bin liners.

A hospital lab microbiologist using S/P Brand Culture Swab Collection and Transport System, distributed by Allegiance Healthcare Corporation, Catalog Number C8552-11 moistened with non-bacteriostatic saline wet swabbed both the drug bins and bin liners and streaked both blood agar and EMB (eosin methylene blue) plates.

Plates were incubated at 35° C and examined for growth at 24, 48, and 72 hour intervals.

The cultures were identified by standard means and reported and categorized. The blood agar plates were photographed for a visual documentation of the relative amount of bacterial growth.

Call Free: 1 800 848 1633 or 1 888 HCL INTL® (425 4685) Fax Free: 1 800 447 2923
Web Site: www.HealthCareLogistics.com • E-mail: hcl@HealthCareLogistics.com

RESULTS

Overall, 84% of all the drug bins that were tested were contaminated with bacterial and mold growth as determined by the test swabbing procedures. In contrast only 32% of the bin liners cultured were contaminated with bacteria and mold growth.

Of the 84% of the drug bins that were contaminated 28 bins (50%) showed positive for 1 organism, 14 bins (25%) for 2 organisms and 5 bins (9%) for 3 organisms. Nine bins (16%) showed no growth. [see Table 1 below for organism count in sampled drug bins]

Table 1: Organism count in sampled drug bins

No Organisms	9	16%
1 - Organism	26	47%
2 - Organisms	14	25%
3 - Organisms	6	11%
	55	100%

Of the 32% of the bin liners that were contaminated 6 liners (24%) showed positive for 1 organism, 1 liner (4%) for 2 organisms and 1 liner (4%) for 3 organisms. Seventeen bin liners (68%) showed no growth. [see Table 2 below for organism count in sample bin liners]

Table 2: Organism count in sampled bin liners

No Organisms	17	68%
1 - Organism	6	24%
2 - Organisms	1	4%
3 - Organisms	1	4%
	25	100%

Comparably fewer bin liners were contaminated than drug bins.

Coagulase negative staph was the commonest contaminant found with 62% of drug bins contaminated with this organism alone or in combination with other bacteria or mold. Pseudomonas was identified in one drug bin in combination with coagulase-negative staph and penicillium. Other bacteria found include diphtheroids and bacillus in combination with staph coagulase-negative or by itself. Mold growth consisted of alternaria, cladosporium, penicillium and one that was not identified. Again, mold growth was in combination with other organisms or by itself. [see Table 3 below for a breakdown of organisms in the contaminated bins]

Table 3: Breakdown of organisms detected in the contaminated bins

Organism	# of bins	%
Staph/diphth	1	2%
Staph/bac	10	18%
Staph coag-neg	17	31%
Bac	3	5%
Diphth	2	4%
Diphth/bac/staph	1	2%
Mold - un "id"	1	2%
Alternaria	2	4%
Alt/bac/staph	3	5%
Pen/bac/staph	1	2%
Cladosporium	1	2%
Pen/bac	1	2%
Staph/pen/pseudo	1	2%
Diphth/alternaria	1	2%
Bac/pen/clado	1	2%
	46	**84%**

Identification of the representative colonies showed that most of the organisms cultured were associated with normal human skin microflora and environmental contamination. Although most microorganisms identified were generally harmless environmental contaminants, some such as the coagulase-negative staph and pseudomonas are capable of causing serious infections. Patients who are compromised by AIDS or by transplantation or cancer therapy, and patients with an increased susceptibility to infection as a result of diabetes or severe burns are particularly at risk.

In contrast, bacillus was the commonest contaminant found in 9% of contaminated bin liners either alone or in combination with other bacteria or mold. Other bacteria found include diphtheroids, staph coagulase-negative. Mold growth consisted of cladosporium and one that was not identified. Again, mold growth was in combination with other organisms or by itself. [see Table 4 below for a breakdown of organisms in the contaminated bin liners]

Table 4: Breakdown of organisms in contaminated bin liners

Organism	# of bins	%
Staph coag-neg	1	4%
Bac	3	5%
Diphth	1	4%
Diphth/bac	1	4%
Mold - un "id"	1	4%
Staph/bac/clad	1	4%
	8	**32%**

DISCUSSION

The results of this study identify an important problem - that being - a high level of contamination on drug bins circulating in the institution. The presence of nonpathogenic members of the skin and environmental bacteria, in relatively high numbers, indicates this poor degree of cleanliness. Dirty drug bins may be a source of transmission of drug-resistant pathogens and should undoubtedly receive more emphasis in infection control programs. One wonders whether such high levels of contamination are acceptable in the institutional pharmacy setting.

Although there is no direct proof that microorganisms from dirty bins can cause nosocomial infections in patients or pose a threat to health care workers, a strong and obvious relationship can be drawn from the results of this study which suggests that contaminated dirty bins could contribute to the nosocomial infection rate.

The CDC recently stated that contact transmission - direct from body surface to body surface or indirect transmission via contaminated inanimate objects is one of the main sources of microorganism transmission.[3] On environmental surfaces, like drug bins, both the presence of pathogenic microorganisms and their ability to survive on the surface of the bin, can contribute to the risk of infection.

Studies have established the persistence of pathogenic microorganisms and their survival in institutional, commercial, and domestic settings. The potential for infectious disease transmission from the environment is further demonstrated by clinical and laboratory studies showing the transmission of microorganisms from person-to-person and via inanimate surfaces, water, hands, food and household surfaces.

Studies have shown that the inanimate environment may serve as a reservoir-disseminator of MRSA and nosocomial VRE transmission. Positive cultures have been isolated from infectious patients' rooms and on gloves, gowns, and uniforms of nurses contacting the patients and also in 42% of personnel not in direct contact with patients but through contamination of their gloves by touching contaminated surfaces. [4]

Furthermore, studies have shown that both bacteria and fungi can live for extended periods of time on plastics [5-8] and microorganisms can efficiently be transferred from plastics to human hands.[9] In turn, a number of studies, often associated with the value of handwashing, have indicated that microorganisms can be transferred from person to person or from health care workers to patients.[10-12]

Contamination in dirty drug bins with potentially pathogenic bacteria, especially MRSA, has the potential for transmission to a larger number of health care workers. Theoretically, contaminated drug bins might pose an unsuspected source of transmission of nosocomial pathogens to health care workers and other patients throughout the institution.[13] These bacteria are transmitted to the hands of the health care worker (usually the nurse) and could subsequently be transmitted to other patients in the course of task of administering medications.
Because of the increased risk that dirty bins could present to patients, the use of these containers throughout a hospital without some sort of cleaning protocol should be reviewed.

A wide variety of patients, from neonates to elderly, are present in the institution. Certain groups such as immunocompromised or those at the extremes of life may be more prone to nosocomial infection. Awareness in pharmacy of the potential for a dirty drug bin to be the source of contamination is critical to sound practice.

While the sample size was small and the results of this study need to be confirmed with a larger sample size, clearly the dirty bins harbored significant numbers of bacteria, probably because the difficulty in cleaning them, lack of cleaning or neglect of cleaning.

Therefore some options should be considered to reduce the possibility of transfer of microorganisms from the plastic infectious dirty bins to patients. Two such options are:

1. the initiation of a bin cleaning protocol
   or
2. the use of bin liners

1. The Initiation of a Bin Cleaning Protocol

The cleaning of dirty bins is generally ignored in day to day practice. Through a series of discussions with hospital pharmacists and a small survey conducted at a midwestern state hospital pharmacy meeting, it was determined that no formal bin cleaning protocols exist in pharmacy. Instead, bin cleaning was initiated on either an individual circumstance where a bin was dirty beyond use or when a regulatory body was going to present itself at the institution.

In most cases there is a lack of awareness of a problem with respect to dirty drug bins and spread of nosocomial infections. Changing pharmacist and nurse behaviors is probably the greatest challenge in addressing this problem.

Health benefits from environmental surface disinfection have been demonstrated in several studies. Cleaning studies have indicated that the disinfectant-cleaner routinely used to clean surfaces in patient rooms decreases the microbial load.One can assume that use of a disinfectant-cleaner on drug bins will also decrease the microbial load. Ideally dirty drug bins should be cleaned on a regular basis, perhaps upon patient discharge, irrespective of their appearance. Dirty drug bins should be washed with disinfectants in automatic washing machines - however, this in many institutions turns out to be impractical and unwieldy.

Effective cleaning management requires a correctly constructed, implemented, and monitored cleaning program. A recent study concluded that visual assessment is a poor indicator of cleaning efficacy and that an ACE audit (Audit for Cleaning Efficacy) gives a better assessment of cleaning programs. It recommends that hospital cleaning regimes be designed to ensure that surfaces are cleaned adequately and that efficacy is assessed with use of internal auditing and rapid hygiene testing. It recommends that after cleaning has taken place, measurements (visual, plus adenosine triphosphate [ATP] or microbial) should be obtained to ensure that the cleaning has been carried out correctly or to an appropriate standard. Data from monitoring should be retained and used in trend analysis and compared with benchmark values that have been obtained during the validation of the cleaning program. [14]

Bin cleaning is often dependent on staff motivation and the time they are given to do this task. The result is irregular and inadequate cleaning of bins, which is often a source of dissatisfaction to both pharmacy and nursing personnel that encounter dirty bins. Adding this procedure during the regular cart filling tasks of pharmacy can potentially add cost to the process.

In a formal bin cleaning protocol, the task of cleaning should be undertaken by a designated and fully informed pharmacy staff person whom should take all necessary precautions. Those responsible for the cleaning should be provided with some protective clothing, such as gowns, gloves and goggles. It should be noted that repeated washing of bins will decrease their lifespan and potentially make them more susceptible to microbial growth. Bins will be in need of regular and on-going replacement.

Overall, though bin cleaning is an option that would be an effective intervention to minimize spread of nosocomial infections potentially caused by dirty drug bins - bin cleaning is costly, time-consuming and potentially harmful to personnel performing the cleaning and to the integrity of the bins over time.

2. The Use of Bin Liners

Bin liners on the other hand are a useful and practical alternative. The use of bin liners as an intervention to minimize the spread of nosocomial infections is a second option. They improve patient care by providing a more consistent, convenient and cost-effective method of maintaining clean patient medication drawers and medical storage bins.

A bin liner is a lightweight polystyrene plastic tray with dimensions slightly less than that of a drug bin that fits into the drug bin covering and shielding its inside surface. This shielding of the inside surface of the drug bin protects the drug bin itself from dirt and residue that can harbor potentially dangerous microorganisms.

A bin liner replacement program can easily be implemented as a procedure during the regular cart filling tasks of pharmacy. Bin liners can be replaced on a regular basis upon discharge of a patient with the new liner being assigned to a newly admitted patient. Whenever a bin liner becomes soiled it can be disposed of and replaced with another clean liner. This could be accomplished both in the pharmacy and up on the nursing unit. No cleaning is required. When compared to a bin cleaning protocol the bin liner replacement program is clearly easier to implement and maintain.

Though exhibiting a lower contamination rate bin liners only minimize microbial growth but do not eliminate it. Bin liners are subjected to the same conditions that the bin is. The difference is that - once dirty - the bin liner can be easily and quickly replaced with a new and clean bin liner whereas a dirty bin needs to be put through a cleaning process.

Study Limitations

The bin liners cultured in this study showed a contamination rate of 32% in comparison to the 84% contamination rate of the dirty bins. It should be noted here that the bin liners used in this study were prototypes and not units from a fully manufactured batch. As such, handling precautions were not initiated to package these prototypes in plastic bags of 25 as the production of sales batches will be packaged. Also, these prototypes were subjected to excessive handling from the manufacturer to distributor and on to the study site (hospital) where the study was conducted. In this process they may have been contaminated.

Although the dirty bins cultured in this study were not contaminated with lifethreatening nosocomial pathogens, 84% of the dirty bins were contaminated. No overt attempt in this study was made to culture bins of patients with prescribed contact precautions for MRSA or VRE. Though none of these serious pathogens showed up in this study the potential exists for contamination of these organisms in dirty bins.

CLOSING

This study makes no attempt to assess the risk of acquiring an infection from a dirty drug bin. No follow up was included to assess if any patient infection resulted from this contamination. The study, however, sought to discover if there is a potential source from which an infection could develop and suggest ways in which this source can be minimized. This study suggests that regular cleaning of bins or use of bin liners between patients should be considered.

Additional studies are needed to determine the identification and transmissibility of nosocomial pathogens through use of dirty drug bins. In further studies, more defined criteria should be set for the numbers of colony forming units that constitute a clean bin versus a dirty bin. Studies should also be initiated to determine the effectiveness of a bin cleaning protocol.

Ample infection control data in the literature demonstrate the cost-benefit of departments that have aggressively pursued interventions to decrease nosocomial infections.[15] In comparison with other widely accepted preventive medical interventions, infection control is recognized as very cost-effective. Reducing nosocomial infections is a proven method to decrease unreimbursed resource utilization and improve patient care and safety.[16]

The prevention of pain and suffering of patients and improvements in quality patient care are obvious additional benefits to the institution and its reputation, which are difficult to quantify. Charges such as laboratory/microbiologic costs, antibiotic costs, pharmacy costs, IV costs related to the delivery of antibiotics, and increased length of stay caused by nosocomial infections can be quantified. On the basis of the potential for these additional costs, the use of bin liners as a cost-effective strategy for the reduction of nosocomial infections and improvement of patient care in the institution makes sense.

Bin liners dramatically reduce the bacterial contamination of drug bins. The results of this initial study should highlight their value in an institutional setting.Bin liners employed as a strategy to reduce nosocomial infections in the institution help improve compliance because they are convenient, quick to use,and low cost in comparison to a bin cleaning program. Consequently, use of these products as part of an infection control program/strategy for pharmacy can have a significant impact on both health outcomes and health care costs.

Although it is recognized that not all nosocomial infections are potentially preventable, more could be prevented with an active intervention-based infection control program. The continued emergence and control difficulties with multidrugresistant pathogens, such as methicillin-resistant S aureus, vancomycin-resistant enterococci, and extended spectrum beta-lactamase producing gram negative bacilli, are major problems in acute care and long-term care facilities alike.

Quality of care and patient safety is the objective of every health care professional. Infection control interventions contribute to both patient safety and quality of care. The use of bin liners as an infection control intervention is pharmacy's contribution.

DEFINITIONS

Alternaria - a genus of fungi; most common species found in a variety of habitats and ubiquitous agents of decay; as decomposers of foodstuffs contribute to spoilage of 20-40% of agricultural output; some alternaria species are gaining prominence as emerging human pathogens, particularly in immunocompromised patients; have been found associated with infections of the cornea, oral and sinus cavities, respiratory tract, nails and skin.

Bacillus - aerobic rod-shaped spore-producing bacterium; often occurring in chainlike formations; a variety of bacterium; a microscopic, rod-shaped vegetable organism; a class of bacteria which are rod-shaped. Belonging to this class are: E. coli, Salmonella, Shigella, Klebsiella, Enterobacter, Clostridia; of these, Bacillus Calmett-Guérin is administered for vaccination against tuberculosis; bacteria causing tetanus, diphtheria, pertussis, and tuberculosis are also rodshaped.

Cladosporium - a genus of fungi having greenish conidiophores with oval or round spores; some species cause superficial fungal infections of the skin of the palms.

Diphtheroid - pseudodiphtheria; false diphtheria; one of a group of local infections, suggesting diphtheria, with occasional symptoms of toxemia, caused by various microorganisms other than the diphtheria bacillus.

Fomite - An inanimate object which, when contaminated with a viable pathogen (bacterium, virus, etc.) can transfer the pathogen to a host; any inanimate object (as a towel or money or clothing or dishes or books or toys etc.) that can transmit infectious organisms from one person to another

Mold - a fungus that produces a superficial growth on various kinds of damp or decaying organic matter

Pathogen - any disease-producing agent especially a virus or bacterium or other microorganism; any disease-causing agent, such as a virus or bacterium; Definition: Organism which can cause disease in another organism.

Penicillium - a saprophytic mold, a genus of the fungi of the class ascomycetes, order aspergillales; they form blue molds which grow on fruits, bread, cheese, etc. Occasionally in man they produce infections of the external ear, skin, or respiratory passageways; common allergens.

Pseudomonas - a genus of small, motile, gram-negative bacilli with polar flagella. Most are saprophytic living in soil and decomposing organic matter; sometimes pathogenic (aeruginosa) in man causing urinary tract or ear infections.

Staphylococcus - spherical gram-positive parasitic bacteria that tend to form irregular colonies; some cause boils or septicemia or infections; Definition: Staphylococcus is a genus of spherical, facultatively anaerobic, Grampositive bacteria in the family Micrococcaceae; they cause a wide range of skin and systemic infections.

REFERENCES

1. Dunagan WC, Murphy DM, Hollenbeak CS, Miller SB. Making the business case for infection control: Pitfalls and opportunities. Am J Infect Control 2002: 30:86-92.

2. Rubino JR. Infection control practices in institutional settings. Am J Infect Control 2001: 29: 241-3

3. Centers for Disease Control and Prevention (Garner JS, Favero MS, eds). Guidelines for isolation precautions in hospitals, 1996. Infection Control Hosp Epidemiol 1996; I:53-80.

4. Cozad, BS, Jones RD. Disinfection and the prevention of infectious disease. AJIC 2003; 31: 243-54.

5. Facklan RR, Washington JA II. Streptococcus and related catalase negative gram-positive cocci. In: Balows A, Hausler WJ Jr, Herrmann KL, Isenberg HD, Shadomy HJ, editors. Manual of clinical microbiology. 5th ed. Washington, DC: American Society for Microbiology; 1991. P. 243.

6. Neely AN, Maley MP. Survival of enterococci and staphylococci on hospital fabrics and plastic. J Clin Microbiology 2000; 38: 724-6.

7. Neely AN. A survey of gram-negative bacteria survival on hospital fabrics and plastics. J Burn Care Rehabil 2000; 21: 523-7.

8. Neely AN, Orloff MM. Survival of some medically important fungi on hospital fabrics and plastics. J Clin Microbiology 2001;39:3360-1.

9. Rangel-Frausto MS, Houston AK, Bale MJ, Fu C, Wenzel RP. An experimental model for study of Candida survival and transmission in human volunteers. Eur J Clin Microbiol Infect Dis 1994; 13:590-5.

10. Larson EL, Aiello AE. Hygiene and health: an epidemiologic link? Am J Infect Control 2001; 29: 232-8.

11. Wong ES. The epidemiology of contact transmission beyond Semmelweis. Infect Control Hosp Epidemiol 2000; 21:77-9.

12. Pittet D, Dharan S, Touveneau S, Sauvan V, Perneger TV. Bacterial contamination of the hands of hospital staff during routine patient care. Arch Intern Med 1999; 159: 821-6.

13. Guinto, CH, Bottone, EJ, Raffalli, JT, Montecalvo, MA, Wormser, GP. Evaluation of dedicated stethoscopes as a potential source of nosocomial pathogens. Am J Infect Control, 2002: 30:499-502.

14. Malik RE, Cooper RA, Griffith CJ. Use of audit tools to evaluate the efficacy of cleaning systems in hospitals. Am J Infect Control 2003: 31:181-7.

15. Fraser VJ, Olsen MA. The business of health care epidemiology: Creating a vision for service excellence. Am J Infect Control 2002: 30: 77-85.

16. Haley RW. Extra charges and prolongation of stay attributable to nosocomial infections: a prospective in the hospital comparison. Am J Med 1981; 70:51-8.

Your small friend, indeed®
Health Care Logistics INC.

Technical Bulletin

The Use of Medication Drawer Bin Liners As An Infection Control Strategy

BACKGROUND

Nosocomial infections are a major problem in health care facilities. It is estimated that 1 in 20 patients (2 million per year) acquire infections during their stay in a hospital, long term care facility, psychiatric center, hospice or other similar facilities. Nosocomial infections from all microorganisms directly cause 19,000 deaths per year and additionally contribute to 58,000 deaths per year. This makes nosocomial infections the 11th leading cause of death in the U.S. Nearly $5 billion is spent annually to identify, track and treat hospital-acquired infections.

In an effort to reduce this problem JCAHO has targeted nosocomial infections and is revising infection control standards which revisions should take effect as early as first quarter of 2005. They want to encourage healthcare organizations to take a more proactive role in infection control. As of January 1, 2004 JCAHO surveyors will be checking accredited organizations on efforts to reduce the risk of healthcare-acquired infections.

DBL Solution, through Health Care Logistics as exclusive distributor, is bringing to market a product that allows pharmacy to make a contribution to the minimization of nosocomial infections - the Daschner Bin Liner - DBL™.

The Daschner Bin Liner - DBL™ was designed "by pharmacists - for pharmacists" to specifically act as a method to eliminate the problem with conventional medication cassette bins/drawers that receive inadequate or no cleaning and become sites for the transmission of nosocomial infections.

Currently there are no standards or documented procedures for the cleaning and reusing of medication bins. Non-critical items such as medication cassette bins and drawers may receive at best a simple cleaning. Though this cleaning may remove some microorganisms, it is inefficient, and in most cases doesn't completely kill them.

Lack of adequate cleaning, however, does not hinder the use of the bin as a container for medication or patient care equipment. Underestimated is the interaction of patient care personnel with these bins/drawers. In the course of providing treatment to patients' invariably cross contact with critical, semi-critical and other non-critical patient care items leads to potential causes of nosocomial infections.

As patient medication drawers and storage bins are frequently reused without the necessary cleaning - the use of the Daschner Bin Liner insures that medication and other patient care equipment that is transported to the patient in a medication bin "reliably and repeatedly" minimizes the risk of nosocomial infections. Bin liners improve patient care by providing a more consistent, efficient and convenient method of maintaining clean patient medication drawers and medical storage bins.

STUDY COMMISSIONED

Pharmacy needs to be aware of the possible contamination of drug bins with microorganisms capable of causing nosocomial infection in patients who are compromised because drug bins used to transport and deliver medications to patients by nurses may contribute to the spread of nosocomial infections in an institution.

With this as a basis, Health Care Logistics commissioned a study in a 300-bed general med/surg hospital to investigate the degree of microbial contamination in dirty bins and compare this to the use of bin liners as an adjunct to minimize the potential for nosocomial infection spread.

METHODOLOGY

Fifty-five (55) drug bins used in the transport and administration of drugs to patients in a 300-bed general med/surg hospital were sampled for bacterial growth.

The drug bins were randomly sampled on medication carts on three active hospital units.

Twenty-five (25) bin liners were sampled from a batch of prototype liners using the same sampling procedure for both the drug bins and bin liners.

A hospital lab microbiologist, using a culture swab moistened with nonbacteriostatic saline, wet swabbed both the drug bins and bin liners and streaked both blood agar and EMB (eosin methylene blue) plates.
Plates were incubated at 35°C and examined for growth at 24, 48, and 72 hour intervals.
The cultures were identified by standard means and reported and categorized.
Select blood agar plates were photographed for a visual documentation of the relative amount of bacterial growth.

Call Free: 1 800 848 1633 or 1 888 HCL INTL® (425 4685) Fax Free: 1 800 447 2923
Web Site: www.HealthCareLogistics.com • E-mail: hcl@HealthCareLogistics.com

RESULTS

Overall, 84% of all the drug bins that were tested were contaminated with bacterial and mold growth as determined by the test swabbing procedures.

In contrast only 32% of the bin liners cultured were contaminated with bacteria and mold growth.

Of the 84% of the drug bins that were contaminated, 28 bins (50%) showed positive for 1 organism, 14 bins (25%) for 2 organisms and 5 bins (9%) for 3 organisms. Nine bins (16%) showed no growth. [see Table 1 below]

Table 1: Organism count in sampled drug bins

No Organisms	9	16%
1 - Organism	26	47%
2 - Organisms	14	25%
3 - Organisms	6	11%
	55	100%

Of the 32% of the bin liners that were contaminated, 6 liners (24%) showed positive for 1 organism, 1 liner (4%) for 2 organisms and 1 liner (4%) for 3 organisms. Seventeen bin liners (68%) showed no growth. [see Table 2 below]

Table 2: Organism count in sampled bin liners

No Organisms	17	68%
1 - Organism	6	24%
2 - Organisms	1	4%
3 - Organisms	1	4%
	25	100%

Comparably fewer bin liners were contaminated than drug bins. [see Tables 3 & 4 below}

Table 3: Breakdown of organisms detected in the contaminated bins

Organism	# of bins	%
Staph/diphth	1	2%
Staph/bac	10	18%
Staph coag-neg	17	31%
Bac	3	5%
Diphth	2	4%
Diphth/bac/staph	1	2%
Mold - un "id"	1	2%
Alternaria	2	4%
Alt/bac/staph	3	5%
Pen/bac/staph	1	2%
Cladosporium	1	2%
Pen/bac	1	2%
Staph/pen/pseudo	1	2%
Diphth/alternaria	1	2%
Bac/pen/clado	1	2%
	46	**84%**

Table 4: Breakdown of organisms in contaminated bin liners

Organism	# of bins	%
Staph coag-neg	1	4%
Bac	3	5%
Diphth	1	4%
Diphth/bac	1	4%
Mold - un "id"	1	4%
Staph/bac/clad	1	4%
	8	**32%**

Identification of the representative colonies showed that most of the organisms cultured were associated with normal human skin microflora and environmental contamination.

Although most microorganisms identified were generally harmless environmental contaminants, some such as the coagulase-negative staph and pseudomonas are capable of causing serious infections. Patients who are compromised by AIDS or by transplantation or cancer therapy, and patients with an increased susceptibility to infection as a result of diabetes or severe burns are particularly at risk.

DISCUSSION

The results of this study identify an important problem - that being - a high level of contamination on drug bins circulating in the institution. The presence of nonpathogenic members of the skin and environmental bacteria, in relatively high numbers, indicates this poor degree of cleanliness. Dirty drug bins may be a source of transmission of drug-resistant pathogens and should undoubtedly receive more emphasis in infection control programs.

Although there is no direct proof that microorganisms from dirty bins can cause nosocomial infections in patients or pose a threat to health care workers, a strong and obvious relationship can be drawn from the results of this study which suggests that contaminated dirty bins could contribute to the nosocomial infection rate.

In this study, given the fact that some pathogenic organisms have been found in medication drawers/bins on the nursing unit, it follows that dirty drug bins can be one link in the complex chain that leads to nosocomial infections. If one breaks that link one weakens the chain. The avoidance of just one nosocomial infection could pay for the bin liners for thousands of patient stays.

The use of bin liners as an intervention to minimize the spread of nosocomial infections is a useful and practical infection control intervention. Bin liners improve patient care by providing a more consistent, convenient and cost effective method of maintaining clean patient medication drawers and medical storage bins.

Cost Comparison Between a Bin Cleaning Protocol versus a Bin Liner Replacement Program

In surveys conducted by DBL/HCL it was determined that no surveyed hospital had a "bin cleaning protocol" in place. Though respondents indicated that they had a "dirty bin" problem and from time to time initiated some procedure to clean the dirty bins – no hospital had a formal program or protocol to clean bins on an on-going basis.

We feel that this may change in the future in light of the results of this study we conducted that indicates that "dirty bins" can contribute to a nosocomial infection problem in an institution.

Given that assumption we considered what a hypothetical bin cleaning protocol for a typical 300-bed hospital would look like.

We took an average 300-bed hospital that performed a 24-hour unit dose cart exchange. In this case 300 bins would be in use and up on the nursing units and 300 bins would be in pharmacy being readied and filled for the next cart exchange. Considering 50 new admits per day, a bin cleaning program would mean having to wash approximately 100 bins per day and replace these dirty bins with 100 clean bins for the new admits.

The cleaning task would be given to a pharmacy technician with a base pay of $13.00 per hour. It was estimated that it would take a technician 5 hours per day to clean the dirty bins or a $65.00 per day expenditure. On a yearly basis (365 days) the basic cost of a "bin cleaning" protocol would be $23,725.

Not considered in this cost are:

1. Pharmacy needs to have approximated 200 additional bins (1/3 of the total bins in use) in stock and available for replacement.There is a cost associated for these additional bins.
2. There is a need for dedicated space to accomplish this bin cleaning task. There is a cost associated for this area.
3. There is a need to use cleaning solutions or wipes (soap, bacteriocide, alcohol, acetone, etc) for cleaning and removing the label adhesive from the dirty bins. There is a cost associated with the necessary cleaning materials.
4. If harsh chemicals (detergents, bacteriocides, alcohol, acetone, etc) are used for the bin cleaning there is the potential to alter the integrity of the bins over time and potentially render them more susceptible to organisms with this repeated cleaning. There would be a cost with replacement of these altered bins.
5. The protocol needs to be maintained by a dedicated person(s).

One can easily see that the total cost of initiating a bin cleaning protocol is in excess of $23,725.

If one considers the time, dedicated personnel and space needed to accomplish this task - costs quickly add up. This doesn't include the cost of the additional bins needed to be put into service to replace those that are being cleaned. When one considers what it would cost and the logistics behind a comprehensive bin cleaning program, the use of bin liners begins to make sense.

Now if we compare the cost of a "bin cleaning protocol" to what a corresponding "bin liner replacement" program would look like for the same hospital – the savings is significant. Given that the average price of a bin liner is $0.28 and 100 bin liners would be replaced each day (2 each for 50 new admits); the yearly cost (365 days) of a bin liner replacement program would be $10,220 or a $13,505 plus savings over a bin cleaning protocol.

The cost of a bin liner is easily justified when one considers the cost to have an employee clean or wash bins. This cost can easily be spread amongst departments as both pharmacy and nursing have an interest in working with clean bins. This cost could also be easily incorporated into a patients admit kit at an additional $0.56 per patient which is certainly nominal in comparison to what the cost of treating a nosocomial infection could be.

Call Free: 1 800 848 1633 or 1 888 HCL INTL® (425 4685) Fax Free: 1 800 447 2923
Web Site: www.HealthCareLogistics.com • E-mail: hcl@HealthCareLogistics.com

SUMMARY

The implementation of bin liners replacement program has the following advantages:

- immediately improves patient care by providing a more consistent, efficient and convenient method of maintaining clean patient medication drawers and medical storage bins
- used for storing and dispensing medications and other patient care supplies in a manner that reduces the risk of infection and cross contamination
- eliminates dirty patient medication cassette bins or drawers and minimizes the accumulation of pathogens
- minimizes contamination to and from patients; cuts down the chance of infection
- saves time! no cleaning involved: whenever a bin liner is contaminated or soiled it can be disposed of and replaced with another liner
- also eliminates unsightly and sticky label adhesive residue on bin from multiple gummed labels that are only partially removed after use
- quick and easy placement in bin with new patient admits; also allows for 'easy transport" of patient meds when patient is transferred to a different unit
- eliminates bin cleaning task, time and hassle
- frees up pharmacy time and improves pharmacy/nursing relations

Bin liners dramatically reduce the bacterial contamination of drug bins. The results of this initial study should highlight their value in an institutional setting. Bin liners employed as a strategy to reduce nosocomial infections in the institution help improve compliance because they are convenient, quick to use, and low cost in comparison to a bin cleaning program. Consequently, use of these products as part of an infection control program/strategy for pharmacy can have a significant impact on both health outcomes and health care costs.

Great ideas evolve out of need. The best solutions are great ideas that are easily and inexpensively implemented. Those are the solutions that last. The use of bin liners is a simple solution in response to a complex problem.

Health Care Logistics, as a partner with DBL Solution, is in the unique position to bring to market this product line that allows pharmacy to make a contribution to the minimization of nosocomial infections. It is HCL's goal to continually expand the bin liner product line beyond the initial introductory bin liner sizes as demand increases.

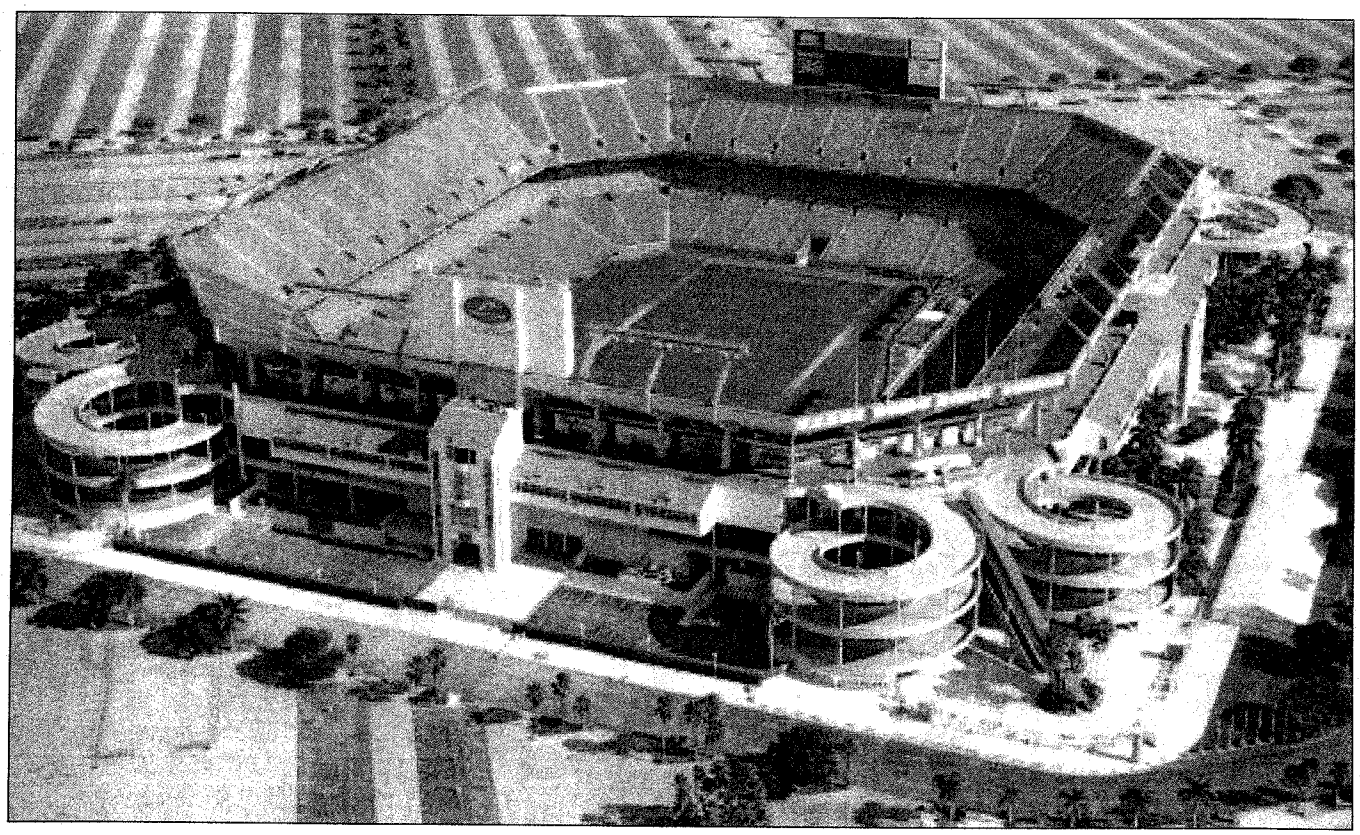
[Complete text of the drug bin/bin liner study cited in this Technical Bulletin is available upon request]

Contact us for product literature on our full line of bin liners!

FACT

It is estimated that 1 in 20 patients (2 million per year) acquire infections during their stay in a hospital, long term care facility, psychiatric center, hospice, or other small facilities.

NOSOCOMIAL INFECTIONS FROM ALL MICROORGANISMS DIRECTLY CAUSE OR CONTRIBUTE TO 90,000 DEATHS PER YEAR - ENOUGH TO FILL MIAMI'S PRO PLAYER STADIUM!



JUST SAY NO socomial™

The use of DBL™ Bin Liners is an excellent way to take a proactive role in infection control and guard against this problem!

Your small friend, indeed®
Health Care Logistics® INC.

TAB B

DEVELOPMED

November 12, 2004

DBL Solution Inc.
835 Oakton Ave.
Romeoville, IL 60446-1619

To Whom It May Concern:

I have to commend your company for coming up with the revolutionary idea of a bin liner product. The problem of dirty bins has been plaguing us in pharmacy for more than 30 years since the concept of unit dose drug distribution systems was conceived and we implemented the use of drug carts. We have long talked about the potential of these dirty bins being a source of hospital-caused infections through cross contamination between health care personnel and patients.

I can't tell you how many times when as a practicing pharmacist my colleagues and myself have complained about the cleanliness of patient drug bins in these carts. Among other things - here are some of the procedures we - from time to time - implemented to try and maintain the cleanliness of bins. We met with our nursing staff and asked them to pay more attention to the cleanliness of their drug bins and spot clean them when they soiled them. We've at times had our technicians schedule regular monitoring and cleaning of bins as needed. We've even sent the drug bins out to our dietary department to have them wash the bins in their dishwashers. One time the wash water was so hot it melted and distorted our bins and we had to buy all new ones. All of these attempts helped the situation on a short-term basis but human nature being as it is - the fix was fleeting and it seemed that we always gravitated back to the dirty bin problem.

I don't practice as a pharmacist today but I work as a consultant to hospital pharmacists. Dirty drug bins are still a problem for them but your bin liners have revolutionized the care and management of these drug bins. Since finding your product on the market I have recommended it to many of my clients. The problem has stared them in the face so long that they couldn't see the forest through the trees. Your simple, one of a kind product solution resolves their problem and now helps immensely.

Now all they have to do is start with clean bins and use your liners. When the liner becomes soiled both nurses and pharmacists are instructed to replace the liner with a new clean one. They are now able to control the situation and always work with clean bins. Your bin liners now provide pharmacy with an opportunity to contribute to the mission of all of healthcare - which is to reduce the potential for hospital-caused infections.

I'm sure you know that there is a lot of interest these days in keeping hospital-caused infections to a minimum. Your product goes a long way in containing that situation from pharmacy's perspective.

I want to thank you for your creative and inventive solution. Keep up the good work. Right now however, your product line is still limited to only a few sizes. All I can ask of you is to continue to add different sizes to your line so that we can use your bin liners in the myriad of different bin sizes that are at use in practice. Please keep me informed as you extend your product line to other bin liner sizes. I will in turn keep my clients apprised of your product.

Sincerely,
DevelopMed Ltd.

Kenneth F. Bober

Kenneth F. Bober. R.Ph.
President

384 Selbourne Road ▾ Riverside,IL 60546 ▾ Phone:708-447-6540 ▾ Fax:708-447-0893 ▾ e-mail:kbober@ameritech.net

Dr. Patricia Bradley
2310 Dalewood Parkway
Woodridge, Illinois 60517

DBL Solutions
835 Oakton Avenue
Romeoville, Illinois 60446-1619

November 10, 2004

DBL Solutions,

I would like to investigate the feasibility of using DBL's bin liner's in our Pharmacy. The medication bins in the main pharmacy and in our Pyxis machines are not regularly maintained and could possibly be contributing to the spread of infection. I believe your product would contribute greatly in decreasing the spread of nosocomial infections in our hospital.

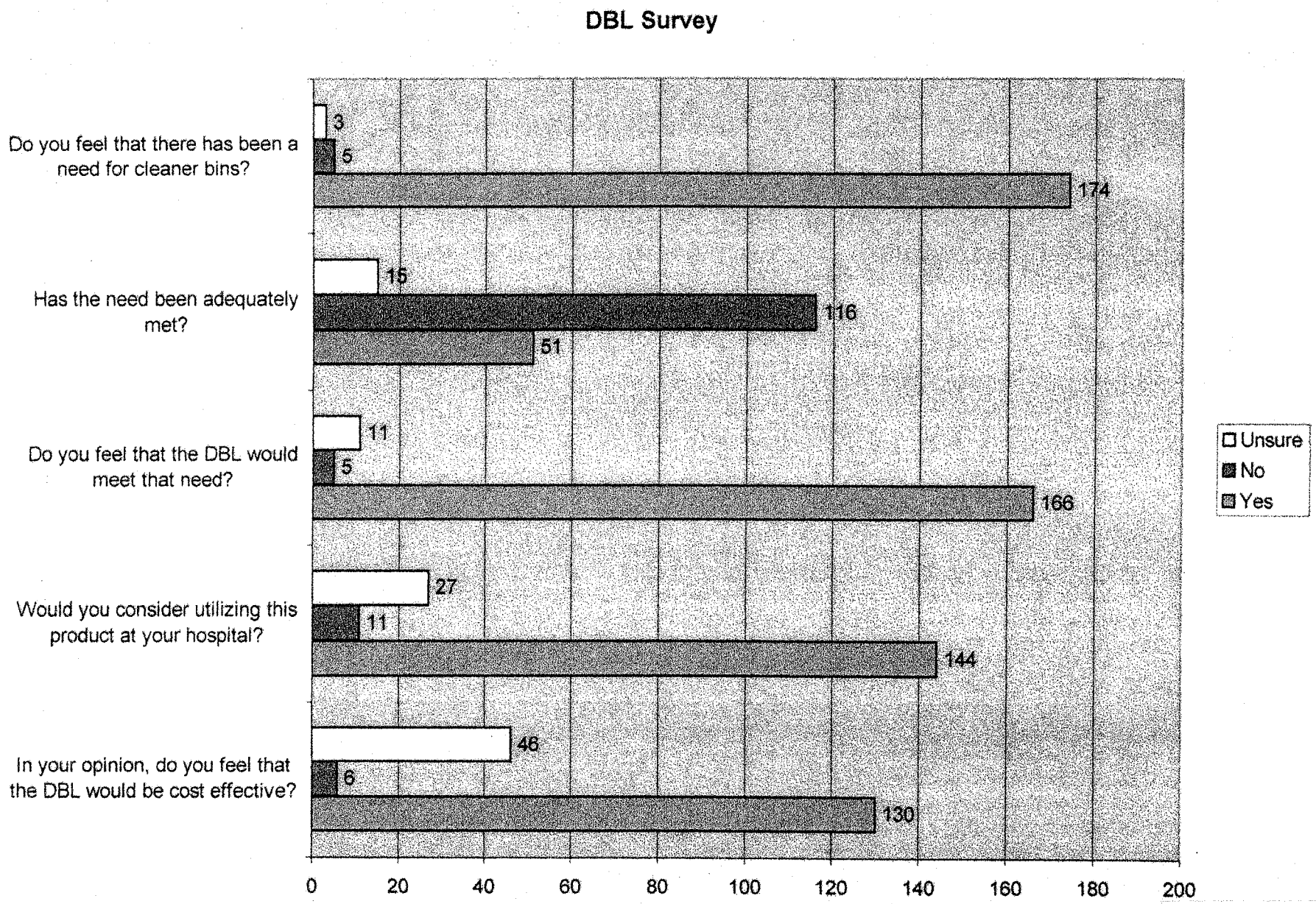
We are all aware that micro-organisms are spread unintentionally and unknowingly on a daily basis by touching of contaminated areas and that handwashing still remains one of the leading preventions of transmitting nosocomial infections. Nurses are in and out of the medication bins and drawers in the Pyxis machines many times in the course of a day, often immediately before contact with the patient. The medication bin is often overlooked during routine cleaning and handwashing is ineffective when a nurse comes in contact with a dirty bin where there are formites laying in wait. I think DBL has come up with an ingenious product to help decrease the spread of this lesser known but just as threatening purveyor of nosocomial infections.

I am convinced your product would enable our Pharmacy to decrease the spread of infection by providing an effective and affordable way to maintain our medication bins. Please send more information about your product so that I may convince our management team that it would be unthinkable not to use this product in our Pharmacy because it is every health professionals responsibility to help decrease the spread of infection to our patients.

Respectfully Yours,

Dr. Patricia Bradley, PharmD

Dr. Patricia Bradley, Pharm D.


DBL Survey
Do you feel that there has been a need for cleaner bins?
Has the need been adequately met?
Do you feel that the DBL would meet that need?
Would you consider utilizing this product at your hospital?
In your opinion, do you feel that the DBL would be cost effective?
3
5
174
15
116
51
11
5
166
27
11
144
46
6
130
0
20
40
60
80
100
120
140
160
180
200
Unsure
No
Yes

TAB C

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Robin E. Hannan	)	ART UNIT: 3637
SERIAL NO.: 10/246,058	)	EXAMINER: Tran, Hanh Van
FILED: August 11, 2004	)	ATTORNEY DOCKET NO. 3439
FOR: Medication Cart Drawer Liner And Method for Using Same to Reduce Nosocomial Infections	)	

DECLARATION OF VIPUL BHATT

I, Vipul Bhatt, declare that I am over 21 years of age and have personal knowledge and am competent to testify to the following. My resume is attached.

1. It is estimated that about 1 in 20 patients (2 million/year) acquire infections in the hospital, known as "nosocomial" infections. It has also been estimated that nosocomial infections from all microorganisms cost nearly $5 billion annually in terms of extra treatment and increased hospital length of stay in the United States (see Cardinal Health Company, Professional Resource Planning & Development, Sept. 2001, Tab A). In addition, nosocomial infections directly cause 90,000 deaths per year and contribute to many more deaths per year, making such infections a "top 10" leading cause of death in the United States (WSJ 3/8/06 article titled: "Hospitals Take Stronger Steps Against Bacteria"). Inappropriate use of antibiotics has lead to the emergence of drug-resistant pathogens, renewing the major challenge of managing pathogens in the hospital setting and demanding appropriate attention and intervention.

2. Often, patients contract nosocomial infections due to their close proximity to and contact with patient care equipment and personnel during treatment. For example, even though patient care equipment or medicine may be sterile, if the container holding the equipment or medicine is not also sterile, an infectious agent may be transmitted from the container and ultimately to the patient. Normally, hospitals and other patient care facilities classify nosocomial infection prevention measures into categories, based on the nature of the patient care equipment involved. Items such as medication carts, bins, bedboards and blood pressure cuffs are deemed noncritical and receive a simple cleaning which is designed to remove rather than to kill microorganisms.

3. An underestimated problem with this prevention measure is the cross-contact between "noncritical" patient care items with "critical and "semicritical" items in the course of treatment. An additional complicating factor is the interaction of patient

care personnel with these items in the course of providing treatment to patients. Thus, regarding medication carts, each drawer is filled with medication in various solid or liquid forms and related patient care equipment. When a patient is released or transferred, the drawer may be cleaned and reused for other patients. However, there are no uniform standards or universal documentary procedures for the cleaning and reusing of medication bins. Bins are frequently reused without the necessary cleaning, in part because a lack of adequate cleaning does not hinder their use. In addition, bins are commonly designated to a specific patient by gummed labels that may be only partially removable after use. Subsequent labels sometimes fall off and the sticky residue from multiple labels becomes another potential host site for bacteria and pathogens, which may be transferred to the medication and then to the patient through repeated contact by the caregiver with the host site in the process of providing care. Further, hospital personnel such as nurses, while held to a much higher standard of care when in surgery, for example, may not wash between medication dispensing, permitting pathogens gained in contact with one patient to be transmitted to another upon subsequent medication cart contact and further dispensing.

4. Given the high costs to the health care system and to hospitals resulting from nosocomial infections, as detailed above, and the long-standing problem and need to address these infections, the failure to address such infections transmitted by medication carts should be puzzling to laypeople. However, I believe that hospital personnel have long failed to recognize the role medication cart dispensing plays in the transmission of nosocomial infections. It is only once this problem is recognized, that a solution such as the present invention can be provided.

5. "Vending machine" type medication carts, known as "Pyxis", "Omnicell", or ADMs (automated dispensing machines) have been used for many years in this country. With these machines, a nurse or other hospital dispensing personnel enters the patient's name or an ID or code corresponding to the patient, and if a pharmacist has previously provided a prescription for the patient as ordered by his/her doctor, the machine will cause a drawer and bin to open with the appropriate medication for that patient. These types of medication carts have always utilized removable, heavy plastic "liners" which fit within the drawers, and which can be removed and cleaned. Unfortunately, this cleaning may not remove drug-resistant pathogens. A much surer way to remove such pathogens is to remove and dispose of the liner, and replace it with a new liner. This is disclosed and claimed by the present invention but, again, without recognizing the problem, the solution was hidden, despite the long-standing need caused by the outbreak of nosocomial infections. Reducing such infections is also helped by dedicating a liner to a patient, such that when a patient leaves a hospital, the corresponding liner is disposed of, and a new liner is provided in that drawer and/or bin location. The present invention also discloses and claims this solution, as well. Again, conventional prior art medication carts have not used this solution, either.

6. U.S. Patent No. 6,039,467 to Holmes fails to address the above-referenced solutions of the present invention. Instead, Holmes perpetuates the flawed nature of prior art medication carts and systems. Thus, Holmes only removes liners but does not dispose

of them and replace them with new liners, as shown in column 9 of Holmes. Further, Holmes fails to dedicate a liner to an individual patient, but instead utilizes a liner with multiple bins for multiple patients, as each Holmes liner is stocked with numerous items that may be selected for any number of patients by a health care provider [see column 8, lines 30-67 of Holmes, as well as the Holmes-type ADMs (automated dispensing machines) in the marketplace, which work this way]. Accordingly, Holmes suffers from the same problems as the prior art, and is unable to limit nosocomial infections as the present invention can. Not surprisingly, Holmes fails to even mention or address nosocomial infections, precisely because Holmes does not address the check of such infections, but is instead concerned with facilitating the delivery of medical supplies, and restocking issues.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: 1/17/08

[Full name]

Pharm D

[professional title/credentials]

Vipul Bhatt
24W630 Eugenia Dr
Naperville, IL 60540
Phone: 630-369-6608
Alternate: 630-846-6000

OBJECTIVE

To obtain a hospital pharmacy position that utilizes skills in pharmaceutical care and management settings

WORK HISTORY AND CLINICAL EXPERIENCE

Adventist Bolingbrook Hospital October 2007 to Present
Clinical Coordinator
Oak Park Hospital: April 2007 to October 2007
Pharmacy Manager
Oak Park Hospital: March 2005 to April 2007
Clinical coordinator
Central Dupage Hospital: May 2003 – March 2005
Pharmacist: critical care, NICU, and pediatrics
Oak Park Hospital: June 2002 - May 2003
Staff Pharmacist
Pharmerica Long-Term Care Pharmacy: 4/15/02 - 5/17/02
Pharmacist consulting for nursing homes
Advocate Health Clinic: 3/11/02 - 4/11/02
Monitoring and counseling for anticoagulation therapy
Northwest Community Hospital: 2/4/02 - 3/8/02
Monitor clinical operations in the critical care unit
Lagrange Memorial Hospital: 1/02/02 - 2/1/02
Daily clinical and pharmaceutical operations
Osco Pharmacy: August 1996 - June 2004
Staff Pharmacist
United States Marine Corps
Active Duty: June 1994 to October 1995
Reserve Duty: October 1995 to June 2000

EDUCATION

Midwestern University: Downers Grove, IL
Pharm D Degree

Ferris State University: Big Rapids, MI
Bachelor of Pharmacy Degree

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Robin E. Hannan	)	ART UNIT: 3637
SERIAL NO.: 10/246,058	)	EXAMINER: Tran, Hanh Van
FILED: August 11, 2004	)	ATTORNEY DOCKET NO. 3439
FOR: Medication Cart Drawer Liner And Method for Using Same to Reduce Nosocomial Infections	)	

DECLARATION OF GARY DAVIS

I, Gary Davis, declare that I am over 21 years of age and have personal knowledge and am competent to testify to the following.

1. It is estimated that about 1 in 20 patients (2 million/year) acquire infections in the hospital, known as "nosocomial" infections. It has also been estimated that nosocomial infections from all microorganisms cost nearly $5 billion annually in terms of extra treatment and increased hospital length of stay in the United States (see Cardinal Health Company, Professional Resource Planning & Development, Sept. 2001, Tab A). In addition, nosocomial infections directly cause 90,000 deaths per year and contribute to many more deaths per year, making such infections a "top 10" leading cause of death in the United States (WSJ 3/8/06 article titled: "Hospitals Take Stronger Steps Against Bacteria"). Inappropriate use of antibiotics has lead to the emergence of drug-resistant pathogens, renewing the major challenge of managing pathogens in the hospital setting and demanding appropriate attention and intervention.

2. Often, patients contract nosocomial infections due to their close proximity to and contact with patient care equipment and personnel during treatment. For example, even though patient care equipment or medicine may be sterile, if the container holding the equipment or medicine is not also sterile, an infectious agent may be transmitted from the container and ultimately to the patient. Normally, hospitals and other patient care facilities classify nosocomial infection prevention measures into categories, based on the nature of the patient care equipment involved. Items such as medication carts, bins, bedboards and blood pressure cuffs are deemed noncritical and receive a simple cleaning which is designed to remove rather than to kill microorganisms.

3. An underestimated problem with this prevention measure is the cross-contact between "noncritical" patient care items with "critical and "semicritical" items in the course of treatment. An additional complicating factor is the interaction of patient

care personnel with these items in the course of providing treatment to patients. Thus, regarding medication carts, each drawer is filled with medication in various solid or liquid forms and related patient care equipment. When a patient is released or transferred, the drawer may be cleaned and reused for other patients. However, there are no uniform standards or universal documentary procedures for the cleaning and reusing of medication bins. Bins are frequently reused without the necessary cleaning, in part because a lack of adequate cleaning does not hinder their use. In addition, bins are commonly designated to a specific patient by gummed labels that may be only partially removable after use. Subsequent labels sometimes fall off and the sticky residue from multiple labels becomes another potential host site for bacteria and pathogens, which may be transferred to the medication and then to the patient through repeated contact by the caregiver with the host site in the process of providing care. Further, hospital personnel such as nurses, while held to a much higher standard of care when in surgery, for example, may not wash between medication dispensing, permitting pathogens gained in contact with one patient to be transmitted to another upon subsequent medication cart contact and further dispensing.

4. Given the high costs to the health care system and to hospitals resulting from nosocomial infections, as detailed above, and the long-standing problem and need to address these infections, the failure to address such infections transmitted by medication carts should be puzzling to laypeople. However, I believe that hospital personnel have long failed to recognize the role medication cart dispensing plays in the transmission of nosocomial infections. It is only once this problem is recognized, that a solution such as the present invention can be provided.

5. "Vending machine" type medication carts, known as "Pyxis", "Omnicell", or ADMs (automated dispensing machines) have been used for many years in this country. With these machines, a nurse or other hospital dispensing personnel enters the patient's name or an ID or code corresponding to the patient, and if a pharmacist has previously provided a prescription for the patient as ordered by his/her doctor, the machine will cause a drawer and bin to open with the appropriate medication for that patient. These types of medication carts have always utilized removable, heavy plastic "liners" which fit within the drawers, and which can be removed and cleaned. Unfortunately, this cleaning may not remove drug-resistant pathogens. A much surer way to remove such pathogens is to remove and dispose of the liner, and replace it with a new liner. This is disclosed and claimed by the present invention but, again, without recognizing the problem, the solution was hidden, despite the long-standing need caused by the outbreak of nosocomial infections. Reducing such infections is also helped by dedicating a liner to a patient, such that when a patient leaves a hospital, the corresponding liner is disposed of, and a new liner is provided in that drawer and/or bin location. The present invention also discloses and claims this solution, as well. Again, conventional prior art medication carts have not used this solution, either.

6. U.S. Patent No. 6,039,467 to Holmes fails to address the above-referenced solutions of the present invention. Instead, Holmes perpetuates the flawed nature of prior art medication carts and systems. Thus, Holmes only removes liners but does not dispose

of them and replace them with new liners, as shown in column 9 of Holmes. Further, Holmes fails to dedicate a liner to an individual patient, but instead utilizes a liner with multiple bins for multiple patients, as each Holmes liner is stocked with numerous items that may be selected for any number of patients by a health care provider [see column 8, lines 30-67 of Holmes, as well as the Holmes-type ADMs (automated dispensing machines) in the marketplace, which work this way]. Accordingly, Holmes suffers from the same problems as the prior art, and is unable to limit nosocomial infections as the present invention can. Not surprisingly, Holmes fails to even mention or address nosocomial infections, precisely because Holmes does not address the check of such infections, but is instead concerned with facilitating the delivery of medical supplies, and restocking issues.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: 1/15/08

Gary W. Davis

[Full name]

MD

[professional title/credentials]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Robin E. Hannan	)	ART UNIT: 3637
SERIAL NO.: 10/246,058	)	EXAMINER: Tran, Hanh Van
FILED: August 11, 2004	)	ATTORNEY DOCKET NO. 3439
FOR: Medication Cart Drawer Liner And Method for Using Same to Reduce Nosocomial Infections	)	

DECLARATION OF ROBERTO J. GARCIA

I, Roberto J. Garcia, declare that I am over 21 years of age and have personal knowledge and am competent to testify to the following. My resume is attached.

1. It is estimated that about 1 in 20 patients (2 million/year) acquire infections in the hospital, known as "nosocomial" infections. It has also been estimated that nosocomial infections from all microorganisms cost nearly $5 billion annually in terms of extra treatment and increased hospital length of stay in the United States (see Cardinal Health Company, Professional Resource Planning & Development, Sept. 2001, Tab A). In addition, nosocomial infections directly cause 90,000 deaths per year and contribute to many more deaths per year, making such infections a "top 10" leading cause of death in the United States (WSJ 3/8/06 article titled: "Hospitals Take Stronger Steps Against Bacteria"). Inappropriate use of antibiotics has lead to the emergence of drug-resistant pathogens, renewing the major challenge of managing pathogens in the hospital setting and demanding appropriate attention and intervention.

2. Often, patients contract nosocomial infections due to their close proximity to and contact with patient care equipment and personnel during treatment. For example, even though patient care equipment or medicine may be sterile, if the container holding the equipment or medicine is not also sterile, an infectious agent may be transmitted from the container and ultimately to the patient. Normally, hospitals and other patient care facilities classify nosocomial infection prevention measures into categories, based on the nature of the patient care equipment involved. Items such as medication carts, bins, bedboards and blood pressure cuffs are deemed noncritical and receive a simple cleaning which is designed to remove rather than to kill microorganisms.

3. An underestimated problem with this prevention measure is the cross-contact between "noncritical" patient care items with "critical and "semicritical" items in the course of treatment. An additional complicating factor is the interaction of patient

care personnel with these items in the course of providing treatment to patients. Thus, regarding medication carts, each drawer is filled with medication in various solid or liquid forms and related patient care equipment. When a patient is released or transferred, the drawer may be cleaned and reused for other patients. However, there are no uniform standards or universal documentary procedures for the cleaning and reusing of medication bins. Bins are frequently reused without the necessary cleaning, in part because a lack of adequate cleaning does not hinder their use. In addition, bins are commonly designated to a specific patient by gummed labels that may be only partially removable after use. Subsequent labels sometimes fall off and the sticky residue from multiple labels becomes another potential host site for bacteria and pathogens, which may be transferred to the medication and then to the patient through repeated contact by the caregiver with the host site in the process of providing care. Further, hospital personnel such as nurses, while held to a much higher standard of care when in surgery, for example, may not wash between medication dispensing, permitting pathogens gained in contact with one patient to be transmitted to another upon subsequent medication cart contact and further dispensing.

4. Given the high costs to the health care system and to hospitals resulting from nosocomial infections, as detailed above, and the long-standing problem and need to address these infections, the failure to address such infections transmitted by medication carts should be puzzling to laypeople. However, I believe that hospital personnel have long failed to recognize the role medication cart dispensing plays in the transmission of nosocomial infections. It is only once this problem is recognized, that a solution such as the present invention can be provided.

5. "Vending machine" type medication carts, known as "Pyxis", "Omnicell", or ADMs (automated dispensing machines) have been used for many years in this country. With these machines, a nurse or other hospital dispensing personnel enters the patient's name or an ID or code corresponding to the patient, and if a pharmacist has previously provided a prescription for the patient as ordered by his/her doctor, the machine will cause a drawer and bin to open with the appropriate medication for that patient. These types of medication carts have always utilized removable, heavy plastic "liners" which fit within the drawers, and which can be removed and cleaned. Unfortunately, this cleaning may not remove drug-resistant pathogens. A much surer way to remove such pathogens is to remove and dispose of the liner, and replace it with a new liner. This is disclosed and claimed by the present invention but, again, without recognizing the problem, the solution was hidden, despite the long-standing need caused by the outbreak of nosocomial infections. Reducing such infections is also helped by dedicating a liner to a patient, such that when a patient leaves a hospital, the corresponding liner is disposed of, and a new liner is provided in that drawer and/or bin location. The present invention also discloses and claims this solution, as well. Again, conventional prior art medication carts have not used this solution, either.

6. U.S. Patent No. 6,039,467 to Holmes fails to address the above-referenced solutions of the present invention. Instead, Holmes perpetuates the flawed nature of prior art medication carts and systems. Thus, Holmes only removes liners but does not dispose

of them and replace them with new liners, as shown in column 9 of Holmes. Further, Holmes fails to dedicate a liner to an individual patient, but instead utilizes a liner with multiple bins for multiple patients, as each Holmes liner is stocked with numerous items that may be selected for any number of patients by a health care provider [see column 8, lines 30-67 of Holmes, as well as the Holmes-type ADMs (automated dispensing machines) in the marketplace, which work this way]. Accordingly, Holmes suffers from the same problems as the prior art, and is unable to limit nosocomial infections as the present invention can. Not surprisingly, Holmes fails to even mention or address nosocomial infections, precisely because Holmes does not address the check of such infections, but is instead concerned with facilitating the delivery of medical supplies, and restocking issues.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: 1/14/08

Robert Garcia Pharm D.
[Full name]

Director, Pharmacy / Materials Management, Advocate Trinity Hosp
[professional title/credentials]

Roberto J. Garcia Pharm. D.
9092 Wolf Road
Willow Springs, Illinois 60480-1622
(708) 351-5267

EMPLOYMENT

Advocate Trinity Hospital **November 2000-Present**
263 Licensed Beds 142 Average Daily Census 800 FTEs
2320 East 93rd Street, Chicago, Illinois 60617

Director, Pharmacy
Reporting to the Vice President, Operations/ Chief Nursing Executive. Responsible for regulatory agency compliance and continuous survey readiness. Directly responsible for the strategic planning, business development, resource management, quality improvement, employee relations, customer satisfaction and the day-to-day operations of Pharmacy Services.

Major Accomplishments in Regulatory Agency Compliance Arena

- Played key role in hospital-wide JCAHO preparation through Trinity's Continuous Survey Readiness team and by harnessing system-wide resources to further our effort. Trinity earned the highest score in the system.
- Served as point-person in developing Advocate Trinity Hospital's Patient Safety Plan and in walking the plan through the approval process up through the Governing Council's approval.
- Standardized hospital-wide meeting minutes by developing a format that included the revised Illinois Medical Studies Act disclaimer and Advocate Trinity Hospital's DOIT CQI format (Define Problem, Outline Causes, Implementation Plan and Track Results).
- Developed educational materials related to survey preparation for leadership and for around the clock sessions for all associates.
- Developed "Patient Safety Handbook" for every clinical area. This booklet includes all sentinel event alerts that have been sent out by JCAHO, a grid which lists out all JCAHO recommendations and existing structures in place as a result of the alerts.

Major Accomplishments in Pharmacy Services Arena

- Led failure mode and effects analysis (FMEA) in the following areas: crash cart readiness process, contrast media administration process, chemotherapy process.
- Advocate Trinity Hospital's Medication Error Reduction effort was described as "best practices" by the JCAHO Surveyor during his visit in November 2001.

- Have served as Co-chair of Advocate-wide Medication Safety Subcommittee of the Pharmacy Director Council.

Our Lady of the Resurrection Medical Center **February 1999 – October 2000**
400 Licensed Beds 200 Average Daily Census 1,200 FTEs
5645 West Addison Street, Chicago, Illinois 60634

Director - Quality Resource Management and Decision Support
Reporting to the Vice President, Patient Services. Responsible for hospital-wide performance improvement, case management, infection control medical staff peer review, decision support and regulatory agency compliance functions.

Major Accomplishments
· Played key role in implementation of "Automatic Antibiotic IV to PO Switch" Policy.
· Active member of the Pharmacy & Therapeutics Committee.
· Implemented process changes in case management that have led to improved hospital viability including: developing a role for a full-time physician advisor, denial appeals specialist, pre-certification specialist, emergency department-based case managers and concurrent coding.
· Have led hospital-wide efforts at preparing for various regulatory agency inspections and have most recently established the Continuous Survey Readiness Team.
· Have coordinated all Quality Council and Medical Staff Performance Improvement/ Utilization Management committees' efforts.

Michael Reese Hospital and Medical Center **October 1997 - December 1998**
2929 South Ellis Avenue, Chicago, Illinois 60616
· 845 Licensed Beds · 250 Average Daily Census · 1,400 FTEs

Michael Reese Hospital and Medical Center is a for-profit academic medical center that provides a full range of healthcare services to Chicago's south side.

Director - Cardiology Product-line and Radiology Services
Reporting to the Vice President, Clinical Services. Responsible for the strategic planning, business development, resource management, quality improvement, employee relations, customer satisfaction and day-to-day operations of the modalities listed below:

Direct responsibility for Cardiac Cath Lab, Cardiac Rehabilitation, Cardiac Infusion Unit, Echocardiography, EKG, Pacemaker Lab, Stress Lab, CT, MRI, Nuclear Medicine, Radiology, Ultrasound, Vascular Lab, Mammography, Bone Densitometry.

Major Accomplishments

· Played a key role in recruiting interventional cardiologists and primary care physicians.
· Eliminated midnight EKG technician coverage by cross-training the midnight respiratory technicians.
· Introduced Flex-pool concept in secretarial role, Echo, Stress Lab and Cardiac Rehab.
· Developed a financial reporting tool for key financial performance indicators.
· Developed Cardiology and medical Imaging Performance Improvement/Quality Improvement reporting format, improved quality indicators.
· Re-engineered Cardiac Catheterization to include Special Procedures Lab cross-training staff for maximum utilization.
· Active member of the Administrative Council and Quality Council.
· Developed Michael Reese Hospital's Monthly Management Operating Report (MOR) Binder which is sent to corporate headquarters.

Saint Anthony Hospital **April 1994 - October 1997**

2875 West 19th Street, Chicago, Illinois 60623
· 184 Licensed Beds · 132 Average Daily Census · 665 FTEs
Saint Anthony Hospital is a Catholic sponsored, nonprofit acute care facility which provides healthcare services to Chicago's west side, paying particular attention to the poor, vulnerable and recent immigrants to this community. This mission is kept viable through sound fiscal management.

Vice President - Operations

Reporting to the Chief Operating Officer. Responsible for the strategic planning, business development, resource management, quality improvement, employee relations, customer satisfaction and day to day operations of the departments listed below:

Admitting, Cardiology, Emergency Department Nursing, Food Services, Housekeeping, Laboratory, Maintenance, Medical Staff Office, Out Patient Services Nursing, Pharmacy, Physical Therapy, Plant Operations, Radiology, Respiratory Therapy, Security.

Major Accomplishments

· Served as "Point Man" for West Side Consolidation Task Force involving successful closure of Saint Cabrini Hospital and consolidation of services into Saint Anthony Hospital. Success was measured by retention of Saint Cabrini Medical Staff (100% were retained). Success was also measured by percent of Saint Cabrini admissions which were captured at Saint Anthony Hospital (72% of Saint Cabrini admissions were retained).

· In preparing for the closure of St. Cabrini Hospital:
-Assisted in the development of the Media & Employee communications plans as well

as the medical staff communications plans.

-Developed staffing plan and worked with Human Resources to resolve union and compensation issues.

-Coordinated computerization of St. Anthony Hospital. Order communications and the Cerner Laboratory System.

-Worked with Materials Management to develop a system for transferring capital equipment physically and on the general ledger from St. Cabrini Hospital to St. Anthony Hospital.

· Re-engineered Ambulatory Services by reorganizing Outpatient Services, Cardiology, Physical Therapy, EEG/EMG, Registration and Security under a single director.
· Oversaw $4.5 million physical reconstruction project involving: Cafeteria, Same-Day-Surgery, Ambulatory Services, Medical Staff Facilities, Call Rooms, Respiratory Therapy, Cardiology, Laboratory, Pharmacy and Physical Therapy.
· Involved in the planning and development of a modern Labor/Delivery /Recovery suite with a capacity for 3,000 annual deliveries.
· Involved in Union negotiations and Union decertification campaign.
· Led hospital-wide preparation effort for regulatory agency inspections which included the JCAHO survey and various HCFA/IDPH inspections.
· Assisted in the initial development of the Performance Improvement Council.

Medical Staff Relationships
· Renegotiated Pathology contract, Pulmonologist contract, Cardiologists' contracts and the Intensive Care Unit Medical Director's contract.

Customer/ Patient Satisfaction
· Emergency Department stat lab work turn-around-time has improved from an average of 52 minutes to 28 minutes. This was accomplished by cross-training the evening shift Laboratory Technicians.
· Roving Pharmacists now pick up orders, deliver medications to nursing units and answer any medication questions from medical or nursing staff.
· The hours of Pharmacy operation have been increased to better serve customer needs. The Pharmacy is now staffed from 6:00 a.m. until 11:00 p.m. on a daily basis.

Elmhurst Memorial Hospital **November 1993 - April 1994**
200 Berteau Avenue
Elmhurst, Illinois 60126

Staff Pharmacist

· Responsible for distribution functions of Pharmacy Services including unit dose and intravenous admixture production.
· Responsible for clinical pharmacokinetic monitoring and dosing of aminoglycosides.

Saint Joseph Medical Center **June 1993 - November 1993**
333 North Madison Street
Joliet, Illinois 60435

Charge Pharmacist
· Management position involving supervision of hospital pharmacy. Main duties involved direct supervision of six employees dispensing unit dose and intravenous medications to hospitalized patients.
· Revamped the narcotics inventory control process.

Saint Anthony Hospital **June 1991 - June 1993**
2875 West 19th Street
Chicago, Illinois 60623

Director, Quality Management
Reporting to the Chief Executive Officer. Directly responsible for implementation of the Total Quality Management philosophy at Saint Anthony Hospital.
· Taught "Managing Quality Improvement, Team Leader Training, and the Team Member Training" courses. Facilitated the Emergency Room and Food service quality improvement teams.
· Worked on special projects with Chief Executive Officer involving market share analysis and medical staff admission pattern analysis.
· Active member of the Quality Council.

Saint Anthony Hospital **August 1988 - June 1993**
2875 West 19th Street
Chicago, Illinois 60623

Staff Pharmacist
· Responsible for distribution functions of Pharmacy Services including dispensing of unit dose and intravenous admixtures.
· Revamped IV piggyback production process by standardizing solution use and by automating IV piggyback standing order label generation.
· Responsible for actively recruiting pharmacy staff. At one point, 60% of all pharmacy staff had been recruited by me.

Mount Sinai Medical Center **June 1988 - September 1990**

California at 15th
Chicago, Illinois 60608

Staff Pharmacist
· Responsible for distribution functions of Pharmacy Services including dispensing of unit dose and intravenous admixtures.
· Standardized expiration dates given to compounded suspensions based on stability data provided by manufacturers and research articles.

Education

2007	University of Michigan College of Engineering Center for Professional Development Lean Healthcare Program
1991-1992	Florida Power and Light (Qualtec) Total Quality Management Training
1984-1988	University of Illinois College of Pharmacy Doctor of Pharmacy (Pharm D)
1981-1984	University of Illinois at Chicago Pre-Pharmacy Undergraduate Curriculum

Licensure
Registered Pharmacist: State of Illinois License Number: 051-037112

Personal
· Family Status: Married Seventeen years to Aeran Garcia, RN MSN MPA.
· Children: One thirteen year old daughter, Gina Garcia.

Foreign Language
· Fluent in Spanish

Computer skills
· Microsoft Office

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Robin E. Hannan	)	ART UNIT: 3637
SERIAL NO.: 10/246,058	)	EXAMINER: Tran, Hanh Van
FILED: August 11, 2004	)	ATTORNEY DOCKET NO. 3439
FOR: Medication Cart Drawer Liner And Method for Using Same to Reduce Nosocomial Infections	)	

DECLARATION OF DAVID RAPER

I, David Raper, declare that I am over 21 years of age and have personal knowledge and am competent to testify to the following. My resume is attached.

1. It is estimated that about 1 in 20 patients (2 million/year) acquire infections in the hospital, known as "nosocomial" infections. It has also been estimated that nosocomial infections from all microorganisms cost nearly $5 billion annually in terms of extra treatment and increased hospital length of stay in the United States (see Cardinal Health Company, Professional Resource Planning & Development, Sept. 2001, Tab A). In addition, nosocomial infections directly cause 90,000 deaths per year and contribute to many more deaths per year, making such infections a "top 10" leading cause of death in the United States (WSJ 3/8/06 article titled: "Hospitals Take Stronger Steps Against Bacteria"). Inappropriate use of antibiotics has lead to the emergence of drug-resistant pathogens, renewing the major challenge of managing pathogens in the hospital setting and demanding appropriate attention and intervention.

2. Often, patients contract nosocomial infections due to their close proximity to and contact with patient care equipment and personnel during treatment. For example, even though patient care equipment or medicine may be sterile, if the container holding the equipment or medicine is not also sterile, an infectious agent may be transmitted from the container and ultimately to the patient. Normally, hospitals and other patient care facilities classify nosocomial infection prevention measures into categories, based on the nature of the patient care equipment involved. Items such as medication carts, bins, bedboards and blood pressure cuffs are deemed noncritical and receive a simple cleaning which is designed to remove rather than to kill microorganisms.

3. An underestimated problem with this prevention measure is the cross-contact between "noncritical" patient care items with "critical and "semicritical" items in the course of treatment. An additional complicating factor is the interaction of patient

care personnel with these items in the course of providing treatment to patients. Thus, regarding medication carts, each drawer is filled with medication in various solid or liquid forms and related patient care equipment. When a patient is released or transferred, the drawer may be cleaned and reused for other patients. However, there are no uniform standards or universal documentary procedures for the cleaning and reusing of medication bins. Bins are frequently reused without the necessary cleaning, in part because a lack of adequate cleaning does not hinder their use. In addition, bins are commonly designated to a specific patient by gummed labels that may be only partially removable after use. Subsequent labels sometimes fall off and the sticky residue from multiple labels becomes another potential host site for bacteria and pathogens, which may be transferred to the medication and then to the patient through repeated contact by the caregiver with the host site in the process of providing care. Further, hospital personnel such as nurses, while held to a much higher standard of care when in surgery, for example, may not wash between medication dispensing, permitting pathogens gained in contact with one patient to be transmitted to another upon subsequent medication cart contact and further dispensing.

4. Given the high costs to the health care system and to hospitals resulting from nosocomial infections, as detailed above, and the long-standing problem and need to address these infections, the failure to address such infections transmitted by medication carts should be puzzling to laypeople. However, I believe that hospital personnel have long failed to recognize the role medication cart dispensing plays in the transmission of nosocomial infections. It is only once this problem is recognized, that a solution such as the present invention can be provided.

5. "Vending machine" type medication carts, known as "Pyxis", "Omnicell", or ADMs (automated dispensing machines) have been used for many years in this country. With these machines, a nurse or other hospital dispensing personnel enters the patient's name or an ID or code corresponding to the patient, and if a pharmacist has previously provided a prescription for the patient as ordered by his/her doctor, the machine will cause a drawer and bin to open with the appropriate medication for that patient. These types of medication carts have always utilized removable, heavy plastic "liners" which fit within the drawers, and which can be removed and cleaned. Unfortunately, this cleaning may not remove drug-resistant pathogens. A much surer way to remove such pathogens is to remove and dispose of the liner, and replace it with a new liner. This is disclosed and claimed by the present invention but, again, without recognizing the problem, the solution was hidden, despite the long-standing need caused by the outbreak of nosocomial infections. Reducing such infections is also helped by dedicating a liner to a patient, such that when a patient leaves a hospital, the corresponding liner is disposed of, and a new liner is provided in that drawer and/or bin location. The present invention also discloses and claims this solution, as well. Again, conventional prior art medication carts have not used this solution, either.

6. U.S. Patent No. 6,039,467 to Holmes fails to address the above-referenced solutions of the present invention. Instead, Holmes perpetuates the flawed nature of prior art medication carts and systems. Thus, Holmes only removes liners but does not dispose

of them and replace them with new liners, as shown in column 9 of Holmes. Further, Holmes fails to dedicate a liner to an individual patient, but instead utilizes a liner with multiple bins for multiple patients, as each Holmes liner is stocked with numerous items that may be selected for any number of patients by a health care provider [see column 8, lines 30-67 of Holmes, as well as the Holmes-type ADMs (automated dispensing machines) in the marketplace, which work this way]. Accordingly, Holmes suffers from the same problems as the prior art, and is unable to limit nosocomial infections as the present invention can. Not surprisingly, Holmes fails to even mention or address nosocomial infections, precisely because Holmes does not address the check of such infections, but is instead concerned with facilitating the delivery of medical supplies, and restocking issues.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: 1/15/08

David Raper (DAVID RAPER)
[Full name]

MD, MBA
[professional title/credentials]

David Raper, MD, MBA
1862 Yale Drive
Louisville, KY 40205
502-724-8401
E-mail: drap488@bellsouth.net
Fax: 502-451-1030

SUMMARY OF EXPERIENCE

SHPS **1/07 to current**

Medical Director, Channel Healthcare

- Consultant on product development
- Support sales and client service
- Direct utilization management, case management, disease management, quality, and analytics

Norton Healthcare **10/05-12/06**

Norton House Calls Physician

- Provide home-based medical services for frail elderly and ill residents of Jefferson County, KY
- Assist in hospice care, hospital care, and discharge planning for patients in program
- Provide physician support for nurse practitioners working in program

Hospice & Palliative Care of Louisville **1/05-7/05**

Associate Medical Director

- Supervised medical management of hospice and palliative care patients admitted to hospice's inpatient unit.
- Directed medical services offered through team home visits.
- Provided education to physicians and other community members about hospice and palliative care.

Contract Management Groups **1980 to current**

Healthcare Provider/ Healthcare Consultant

- Provide clinical and administrative services to contractors responsible for delivery of emergency medical care. Current customers include Team Health, United Emergency Services, and Kentuckiana Emergency Physicians.

Progressive Medical & Rehabilitation Group, Louisville, KY **6/03-12/03**

Consultant

- Identified and developed new business opportunities
- Recruited staff physician
- Developed quality assurance program

Humana Military Healthcare Services, Louisville, KY

Consultant, Finance/Resource Sharing **2/02-9/02**

- Introduced systematic, organized, and effective method of data gathering and analysis useful in the early identification of new business opportunities
- Developed approach to initial site visits with customers (military treatment facilities); improved and enhanced relationships with staff of military treatment facilities visited; added credibility to Finance/ Resource Sharing teams making site visits
- Made a number of recommendations leading to improved productivity and organizational structure of Resource Sharing unit

Humana Inc, Louisville, KY

Associate Medical Director Kentucky Market Office **1999-2001**

- Directed medical management for 250,000 member health plan, including inpatient concurrent review, pre-certification activities, and oversight of hospitalists
- Identified the need for and collaborated in the development of process improvement programs for medical management department
- Assisted in writing policy and procedure manual used by all Humana Grievance and Appeals units
- Led market efforts to redesign pharmacy review and notification system
- Supported sales, provider relations, government relations, and contracting staff
- Served on credentials, grievance and appeals, communication, safety, and quality committees of Humana-KY
- Represented Humana on governor's HIV task force and state association of health plans
- Served as Interim Director of Medical Operations following reorganization of Humana-KY
- Led initial implementation of Personal Nurse program in Kentucky market
- Directed organization of formal provider appeals unit for Humana-KY

Hope Medical Clinic, Oriental, NC **1997-1999**

An independent nonprofit clinic designed to serve the uninsured and under-insured residents of Pamlico County and surrounding areas; affiliated with Episcopal Church Diocese of East Carolina

- Conceived the idea for and collaborated in the creation of the Hope Clinic
- Served as board member of the clinic

Aurora Medical Center, Aurora, NC **1996-1998**

Formerly a federally funded Rural Health Center, the Aurora Medical Center is now owned and operated by Beaufort County Hospital, Washington, NC. The clinic provides primary health care services to a largely indigent population in rural coastal NC.

Medical Director

Oversaw operations of the clinic including budgeting, grant writing, staffing, training, community outreach, and expansion of health care services; developed clinical programs and innovative support services for the medical center

- Actively recruited two physician assistants and one family practice MD to work at medical center
- Conceived the idea for and collaborated in the development of a program of specialty consultation services for patients of the medical center
- Implemented a community outreach program to raise awareness concerning various health issues via public speaking engagements, use of print and broadcast media, and involvement in civic events
- Initiated volunteer services program to assist with patient needs and donation of equipment to medical center
- Developed and implemented a health screening program for migrant workers in medical center's service area; provided for Spanish language training for center's staff; led efforts to develop area-wide coordination of information and services relevant to migrant population; co-wrote successful grant application awarding funds for involvement of physician assistants in the care for migrant workers
- Created and implemented indigent prescription drug program to assist patients in obtaining prescriptions
- Collaborated in medical center building redesign to improve patient access and work environment
- Led effort to transform medical center from Rural Health Center to a department of Beaufort County Hospital
- Implemented improved information system to better track and report practice data; instituted e-mail system for improved communication with hospital headquarters located 35 miles away
- Served as full-time health care provider

St. Anthony Medical Center, Louisville, KY **1992-1995**

A nonprofit medical center with 15,000 emergency department visits per year owned and operated by the Sisters of St. Francis, Inc.

Emergency Department Director

Responsible for scheduling, dispute resolution, and general management of staff of ten physicians on behalf of a large contract management group providing emergency department services

- Served on professional review, family practice, emergency department review, and infection control committees

- Led effort to establish a quality improvement program for the department that included joint physician-nurse reviews of care; program later received commendation from JCAHO

- Assisted in development and implementation of clinical paths for high volume/high risk diagnoses designed to improve care, reduce costs, and reduce length of stay

- Collaborated in department's renovation and redesign to improve patient care and work environment

Audubon Hospital, Louisville, KY **1986-1992**

A for-profit medical center with 45,000 emergency department visits per year owned and operated initially by Humana and subsequently by Columbia; co-founder of single-hospital private group of 15 physicians providing emergency department services; group employed four office staff, performed its own billing and collecting, and generated annual revenues of $3,000,000

Emergency Department Director, 1991
Responsible for scheduling, dispute resolution, and general management of physician staff as well as oversight of activities of group's office staff

- Served on professional review, emergency department, and city-county emergency services committees

- Restructured group's benefits program to fully conform to IRS guidelines

- Full-time practice of emergency medicine

EDUCATION

Rocky Mount Senior High School, Rocky Mount, NC, Diploma 1969
University of Louisville, Louisville, KY, BA Psychology 1969-1973
East Carolina University, Greenville, NC, 2 years of Nursing School, 1973-1975; 1 year of Master's studies in Child Development and Family Relations, 1974-1975
University of North Carolina, Chapel Hill, NC, MD 1975-1978
Post-graduate medical training, 6 months Internal Medicine at St. Elizabeth's Hospital, Youngstown, OH followed by 16 months Family Medicine at University of Louisville, KY, 1979-1980
Campbell University, Buies Creek, NC, 1 year of law studies, 1984-1985
Regent University, Virginia Beach, VA, MBA 1995-1998
Duke University Certificate Program in Nonprofit Management, 1999
Presently enrolled in Master of Theological Studies, Saint Meinrad School of Theology, St. Meinrad, IN

CERTIFICATION AND LICENSURE

Board certification in Hospice and Palliative Medicine 2006
Diplomate, American Board of Hospice and Palliative Medicine
Board certification in Emergency Medicine from American Board of Emergency Medicine in 1986; re-certified in 1997
Fellow, American Academy of Emergency Medicine

Fellow, American College of Emergency Medicine
Fellow, University of Virginia, Center for Biomedical Ethics
Medical licensure: North Carolina, Kentucky, Virginia, Tennessee

PROFESSIONAL ASSOCIATIONS

Member, American Academy of Hospice and Palliative Medicine
Member, Southern Medical Association
Member, Jefferson County Medical Society
Member, Community Health Committee, Jefferson County Medical Society
Member, Supplies Over Seas (SOS) Committee, Jefferson County Medical Society
Member, Kentucky Medical Association
Member, Committee on the Uninsured, Kentucky Medical Association
Member, American Medical Association
Member, American Academy of Home Care Physicians
Member, American Geriatrics Society
Member, Board of Directors, Healing Companions, Inc.
Member, American College of Medical Quality
Member, Disease Management Association of America

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Robin E. Hannan	)	ART UNIT: 3637
SERIAL NO.: 10/246,058	)	EXAMINER: Tran, Hanh Van
FILED: August 11, 2004	)	ATTORNEY DOCKET NO. 3439
FOR: Medication Cart Drawer Liner And Method for Using Same to Reduce Nosocomial Infections	)	

DECLARATION OF RUSS CARRELL

I, Russ Carrell, declare that I am over 21 years of age and have personal knowledge and am competent to testify to the following. My resume is attached.

1. It is estimated that about 1 in 20 patients (2 million/year) acquire infections in the hospital, known as "nosocomial" infections. It has also been estimated that nosocomial infections from all microorganisms cost nearly $5 billion annually in terms of extra treatment and increased hospital length of stay in the United States (see Cardinal Health Company, Professional Resource Planning & Development, Sept. 2001, Tab A). In addition, nosocomial infections directly cause 90,000 deaths per year and contribute to many more deaths per year, making such infections a "top 10" leading cause of death in the United States (WSJ 3/8/06 article titled: "Hospitals Take Stronger Steps Against Bacteria"). Inappropriate use of antibiotics has lead to the emergence of drug-resistant pathogens, renewing the major challenge of managing pathogens in the hospital setting and demanding appropriate attention and intervention.

2. Often, patients contract nosocomial infections due to their close proximity to and contact with patient care equipment and personnel during treatment. For example, even though patient care equipment or medicine may be sterile, if the container holding the equipment or medicine is not also sterile, an infectious agent may be transmitted from the container and ultimately to the patient. Normally, hospitals and other patient care facilities classify nosocomial infection prevention measures into categories, based on the nature of the patient care equipment involved. Items such as medication carts, bins, bedboards and blood pressure cuffs are deemed noncritical and receive a simple cleaning which is designed to remove rather than to kill microorganisms.

3. An underestimated problem with this prevention measure is the cross-contact between "noncritical" patient care items with "critical and "semicritical" items in the course of treatment. An additional complicating factor is the interaction of patient

care personnel with these items in the course of providing treatment to patients. Thus, regarding medication carts, each drawer is filled with medication in various solid or liquid forms and related patient care equipment. When a patient is released or transferred, the drawer may be cleaned and reused for other patients. However, there are no uniform standards or universal documentary procedures for the cleaning and reusing of medication bins. Bins are frequently reused without the necessary cleaning, in part because a lack of adequate cleaning does not hinder their use. In addition, bins are commonly designated to a specific patient by gummed labels that may be only partially removable after use. Subsequent labels sometimes fall off and the sticky residue from multiple labels becomes another potential host site for bacteria and pathogens, which may be transferred to the medication and then to the patient through repeated contact by the caregiver with the host site in the process of providing care. Further, hospital personnel such as nurses, while held to a much higher standard of care when in surgery, for example, may not wash between medication dispensing, permitting pathogens gained in contact with one patient to be transmitted to another upon subsequent medication cart contact and further dispensing.

4. Given the high costs to the health care system and to hospitals resulting from nosocomial infections, as detailed above, and the long-standing problem and need to address these infections, the failure to address such infections transmitted by medication carts should be puzzling to laypeople. However, I believe that hospital personnel have long failed to recognize the role medication cart dispensing plays in the transmission of nosocomial infections. It is only once this problem is recognized, that a solution such as the present invention can be provided.

5. "Vending machine" type medication carts, known as "Pyxis", "Omnicell", or ADMs (automated dispensing machines) have been used for many years in this country. With these machines, a nurse or other hospital dispensing personnel enters the patient's name or an ID or code corresponding to the patient, and if a pharmacist has previously provided a prescription for the patient as ordered by his/her doctor, the machine will cause a drawer and bin to open with the appropriate medication for that patient. These types of medication carts have always utilized removable, heavy plastic "liners" which fit within the drawers, and which can be removed and cleaned. Unfortunately, this cleaning may not remove drug-resistant pathogens. A much surer way to remove such pathogens is to remove and dispose of the liner, and replace it with a new liner. This is disclosed and claimed by the present invention but, again, without recognizing the problem, the solution was hidden, despite the long-standing need caused by the outbreak of nosocomial infections. Reducing such infections is also helped by dedicating a liner to a patient, such that when a patient leaves a hospital, the corresponding liner is disposed of, and a new liner is provided in that drawer and/or bin location. The present invention also discloses and claims this solution, as well. Again, conventional prior art medication carts have not used this solution, either.

6. U.S. Patent No. 6,039,467 to Holmes fails to address the above-referenced solutions of the present invention. Instead, Holmes perpetuates the flawed nature of prior art medication carts and systems. Thus, Holmes only removes liners but does not dispose

of them and replace them with new liners, as shown in column 9 of Holmes. Further, Holmes fails to dedicate a liner to an individual patient, but instead utilizes a liner with multiple bins for multiple patients, as each Holmes liner is stocked with numerous items that may be selected for any number of patients by a health care provider [see column 8, lines 30-67 of Holmes, as well as the Holmes-type ADMs (automated dispensing machines) in the marketplace, which work this way]. Accordingly, Holmes suffers from the same problems as the prior art, and is unable to limit nosocomial infections as the present invention can. Not surprisingly, Holmes fails to even mention or address nosocomial infections, precisely because Holmes does not address the check of such infections, but is instead concerned with facilitating the delivery of medical supplies, and restocking issues.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: 1/23/08

Russell Connell
[full name]

System Specialist Cardinal Health / Pyxis
[professional title/credentials]

Russell Carrell
38 Ridgewood Rd
Elk Grove, Illinois 60007
(847) 290-1026 / (847) 490-4911
RCarrell@SBCGlobal.net

Summary of Experience

Over 20 years of application installation, service, project management, technical support and training. Demonstrate strength in quickly understanding and handling complex technical and operational issues.

11/2000 to Present **CARDINAL HEALTH –AIS (Automation and Information Services), Chicago, IL**
Publicly held $50 billion in sales, one of the largest US wholesalers of pharmaceuticals, surgical and hospital supplies, and other specialty pharmaceutical products.

System Specialist, Report to Customer Service Manager (CSM).
Managing and supporting the Pyxis information system technologies for over 40-hospitals in the Chicago land area. Project Manager for all new installations, conversions and upgrades. Hands-on responsibility to coordinate support activities with Pharmacy, IS, Facilities and Nursing. Other responsibilities include, provide system support, upgrades, and virus protection while mentoring new specialists.

11/1995 to 11/2000 **CARDINAL HEALTH –AIS (Automation and Information Services), Chicago, IL**

Application Specialist, Report to Customer Service Manager (CSM).
Project Manager supporting the Pyxis information system technologies for approximately 10-hospitals in the Chicago land area. Responsible for new product installations, upgrades and conversions. Recommend and develop strategies to improve product functionality to meet customer requirements. Supported platforms and software include:

- **Windows XP; Windows NT/2000; O/S2.**
- Cardinal Health Products & Services include: PYXIS MedStation 2000; Pyxis MedStation 3000; Pyxis MedStation 3500; Pyxis Supply 30; Pyxis Anesthesia System, Pyxis Par-X (Symbol Barcode).
- Managing projects and customers utilizing Cardinal internal systems: **PeopleSoft CRM, PAR (PM tool).**

OTHER EXPERIENCE:

BUDGET RENT A CAR, Lisle, IL
Help Desk Manager, Supported rental offices nationwide.

CONTINENTAL HEALTH CARE, Libertyville, IL
INSTALLATION SPECIALISTS, Hospital materials management systems.

ICC, Buffalo Grove, IL
Enhanced 911 systems for police and fire.